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Does Cognitive Behavioural Analysis System of Psychotherapy improve interpersonal functioning in patients affected by persistent depression and what can research tell us about the theoretical model this therapy is based on?

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Dziękuję.

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1.Thesis Abstract

Background. Cognitive Behavioural Analysis System of Psychotherapy (CBASP) has been developed to treat individuals affected by persistent depressive disorder (PDD). There is a growing number of empirical studies to suggest that CBASP is effective in treating chronically depressed population. Taking into account these findings as well as the chronic and debilitating nature of persistent depression, it can be invaluable, when planning treatment, to understand the factors contributing to and maintaining this condition, as well as mechanisms of change involved in CBASP.

Purpose. A systematic review aimed to establish the quality of evidence indicating the effectiveness of CBASP when addressing difficulties with interpersonal functioning which are believed to be causing and maintaining depressive symptoms according to the theory of persistent depression developed by McCullough (2000). McCullough hypothesised that childhood trauma leads to an impairment in the cognitive-emotional development, which then leads to interpersonal difficulties that result in depressive symptoms. An empirical study aimed to identify the strength of the relationships between different constructs in the theoretical foundations of CBASP.

Methods. A systematic literature search was conducted identifying research reporting the effects of CBASP intervention on interpersonal functioning in the clinical samples affected by PDD or depression of chronic nature but not meeting all the criteria for PDD. The search yielded nine papers which met inclusion and exclusion criteria. The Effective Public Health Practice Project quality assessment tool was employed to assess the quality of the included studies. In order to collect data for empirical study, a cross-sectional design was used. Clinicians working in the mental health teams in the local board were asked to identify adult patients on their caseloads who were affected by PDD. The clinicians were then invited to introduce the study to these patients and, if the patient showed an interest, offer them a questionnaire pack to read at home. Thirty-two patients with PDD completed and returned a set of questionnaires measuring childhood trauma, pre-operational functioning/reflective functioning, interpersonal difficulties, and depressive symptoms. A series of multiple regression analyses were used to analyse the results.

Results. The systematic review provided evidence supporting the hypothesis that CBASP intervention leads to an improvement in the area of interpersonal functioning. The majority of the assessed studies demonstrated the improvements on the measures of interpersonal functioning, while all of the studies showed reductions in depressive symptoms. The methodological quality of the studies has been evaluated to be of good or very good standard which strengthened the reliability and validity of the results. Findings from the empirical study, somewhat surprisingly, failed to demonstrate the hypothesised association between childhood trauma, pre-operational thinking, interpersonal difficulties and the severity of depression. Childhood adversity, pre-operational thinking and interpersonal difficulties did not predict the severity of depressive symptoms. The relationship between childhood trauma and interpersonal functioning, as well as interpersonal functioning and depression, did not reach statistical significance, even when the subscale of the Inventory of Interpersonal Problems (Horowitz, Alden, Wiggins, & Pincus, 2000) measuring a hostile submissive interpersonal style associated with persistent depression, was entered into the model.

Discussion. The findings from the first chapter of this thesis provide evidence suggesting that CBASP intervention leads to an improvement in the area of interpersonal functioning and reduction in depressive symptomatology. Importantly, the review's results demonstrated that while the assessed studies were primarily of good quality, more studies investigating specific mechanisms of change involved in the CBASP intervention are needed. The analyses which were part of the empirical study revealed the lack of associations between the constructs used by McCullough in his theory of persistent depression. While it is possible that the relationships between the discussed constructs are weaker than previously established, there have been a number of methodological limitations, such as a potentially unrepresentative sample and its small size, which might have contributed to the absence of predicted effects.

2. Lay summary of thesis

Introduction. Depression is a mental health condition that is often disabling and challenging for people who are affected by it. In about one third of cases, depression has a chronic nature meaning it persists over a number of years. Cognitive Behavioural Analysis System of Psychotherapy (CBASP) is a therapy that has been developed to treat chronic depression. CBASP was developed based on a theory that describes chronic depression as happening when, as a result of early negative experiences, an individual has difficulties with interpersonal interactions.

Aims and methods. The first part of this thesis aimed to determine whether there is evidence in the current research literature supporting the idea that CBASP leads to less difficulties in interpersonal interactions. It also sought to establish whether the research studies in the area are of good methodological quality. A second study aimed to explore the nature of relationships between childhood trauma, cognitive-emotional development, interpersonal functioning, and chronic depression.

Main findings. The findings in this thesis suggest that CBASP intervention is helpful to individuals affected by chronic depression, in that, it leads to less interpersonal difficulties, and helps to reduce depressive symptoms. The first study found that the evidence which showed these improvements is based on studies which have been rated, on the whole, as being of good quality. The second study found no evidence for relationships between childhood trauma, cognitive-emotional development, interpersonal difficulties, and depressive symptoms suggesting that these relationships might be weaker than previously thought.

Conclusions. The findings from this thesis suggest that CBASP leads to an improvement in interpersonal difficulties and depressive symptoms. Future research can focus on identifying specific aspects of interpersonal functioning that improve following this intervention to help therapists better understand the nature of difficulties addressed by CBASP. Importantly, no supporting evidence was found for relationships between the different factors which are believed to cause and maintain chronic depression. Given the lack of research in this area, in order to be able to draw strong conclusions, more studies investigating the theoretical model CBASP is based on are necessary.

3. Chapter 1: Systematic review

Effects of Cognitive Behavioural Analysis System of Psychotherapy on interpersonal functioning in individuals affected by persistent depression?

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This chapter was written in accordance with the author guidelines for the Journal of Clinical Psychology and Psychotherapy (Appendix A).

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3.1. Abstract

Background. Cognitive Behaviour Analysis System of Psychotherapy (CBASP) has been specifically designed to treat patients affected by Persistent Depressive Disorder (PDD). CBASP addresses the interpersonal functioning of the individual through a number of therapeutic techniques. This review sought to determine whether CBASP improves interpersonal functioning in chronically depressed patients.

Methods. A systematic literature search was conducted for research measuring the effects of CBASP on interpersonal functioning in the individuals affected by PDD or depression of chronic nature but not meeting all the criteria for PDD. The Effective Public Health Practice Project quality assessment tool was used to evaluate the quality of the included papers.

Results. Nine papers met the inclusion and exclusion criteria. Six out of nine studies have revealed the improvements on the measures of interpersonal functioning, while all of the studies demonstrated improvements in depressive symptomatology following the CBASP intervention. The methodology of the studies under investigation has been found to be of a good standard, with the majority of the papers being assigned strong or moderate ratings which is indicative of the reliability and validity of the results.

Limitations. The review yielded a relatively small number of papers due to the limited research into the area, which might have affected the generalisability of the findings. There was also a lack of consistency among the studies regarding the definition of interpersonal functioning and measures used to assess it. Future avenues for research in this area include identifying specific aspects of interpersonal functioning which are associated with a reduction in chronic symptoms in order to help practitioners tailor psychological interventions for this population.

Key words: CBASP; interpersonal functioning; chronic depression; persistent depression

3.2. Introduction

3.2.1. Persistent depression

The prevalence of depressive disorders in Western countries is estimated at 17-19% (Jacobi et al., 2004; Kessler et al., 2005) and in about 20-35% cases the nature of depression is persistent (Arnow & Constantino, 2003; Dunner, 2001; Gilmer et al., 2005; Klein & Santiago, 2003). The average duration of persistent depression (PD) is approximately 20 years (Gilmer et al., 2005; Kocsis, 2003). With its relatively high prevalence, depression can be one of the major factors affecting an individual's quality of life and a country's economy (Greenberg et al., 2003; Murray et al., 2012).

The fifth and latest edition of The Diagnostic and Statistical Manual of Mental Disorders (DSM-V) (American Psychiatric Association, 2013) has slightly amended the diagnoses and definitions of depressive disorders using the duration of an episode as one of the main criterion. In order to meet criteria for a major depressive disorder (MDD), five or more symptoms from the suggested list (with at least one of them being depressed mood or loss of interest or pleasure) have to be present during the same two week period, and represent a change from previous functioning (see Appendix B). DSM-V also merged presentations of chronic depression and dysthymia (characterised in DSM-IV by milder depressive symptoms lasting for at least two years (American Psychiatric Association ,1994) into one persistent depressive disorder (PDD). PDD is diagnosed if depressed mood continues to last for most of the day, more days than not, for at least two years, and is accompanied by two other symptoms from the suggested list (see Appendix C).

Although several types of PD can be identified in the literature i.e. dysthymia, chronic major depression, recurrent major depression with incomplete remission during episodes and double depression (Dunner, Lipschitz, Pitts, & Davies, 2005; Kocsis, 2000), there are no established differences in their aetiology. PD, which is often referred to as 'chronic depression' in research literature, can be seen as an umbrella term with its subcategories showing more similarities than differences (Dunner et al. 2005;

Klein & Santiago, 2003). For the purpose of this review, chronic presentations of depression will be referred to as PDD as per DSM-V terminology.

PDD has been shown to lead to a significantly higher global burden of disease and associated costs than episodic depression (Arnow & Constantino, 2003; Greenberg et al., 2003). For example, chronic forms of depression are associated with higher use of health care (Gilmer et al., 2005; Klein, Schwartz, Rose, & Leader, 2000; McFarland & Klein, 2005). In the study by Klein et al. (2000), patients with a diagnosis of dysthymic disorder were eight times more likely to be admitted to a psychiatric unit than patients with episodic major depressive disorder. In many cases, PDD persists despite pharmacological or therapeutic intervention (Ghaemi, 2008; Kocsis, 2003). Interestingly, about 70% individuals with PDD report onset before the age of 21 years old (Cassano, Akiskal, Perugi, Musetti, & Savino, 1992; Keller et al., 2000). In fact, depression with a chronic course has been often shown to be associated with early childhood adversity such as neglect as well as physical or sexual abuse (Chapman et al., 2004, Korkeila et al., 2005; Lizardi et al., 1995; Wiersma et al., 2009). Chronically depressed patients also report more difficulties with psychosocial functioning (Arnow & Constantino, 2003; Berndt et al., 2000), and, in particular, interpersonal skills (Hammen & Brennan, 2002; Miller et al., 1998; Petty, Sachs-Ericsson, & Joiner, 2004). While the impact of depression on mental health has been well documented, the mechanisms leading to and perpetuating depressive symptoms are less understood. Therefore, this review will focus on research studies investigating the effects of CBASP on interpersonal functioning. It will specifically explore the quality of existing literature in order to be able to draw well-grounded conclusions.

3.2.2. Interpersonal functioning and chronic depression

Interpersonal difficulties can include a broad range of problems related to social interaction and engagement within both intimate relationships or broader interpersonal situations (Hartmann, Zeeck, & Barrett, 2010). There is a strong evidence base emphasising the key role of interpersonal functioning in mental health. Being able to form and maintain secure and fulfilling interpersonal relationships has been argued to be essential to an individual's

happiness and overall wellbeing (e.g. Berscheid & Peplau, 1983). In contrast, difficulties within the area of interpersonal functioning have been linked to a range of psychological problems such as depression (e.g. Barrett & Barber, 2007), anxiety (e.g. McEvoy, Burgess, Page, Nathan, & Fursland, 2013), eating disorders (e.g. Arcelus, Haslam, Farrow, & Meyer, 2013), and personality disorders (e.g. Pincus & Wiggins, 1990). Furthermore, difficulties within interpersonal functioning have been suggested to be one of the major factors causing and maintaining depressive episodes. Insecure attachment patterns, submissiveness, lack of assertiveness, social disinhibition, and poor interpersonal skills have been found to predict both the onset and the maintenance of depression (Barrett & Barber, 2007; Constantino et al., 2008; Coyne, 1976; Eberhart & Hammen, 2006; Joiner & Timmons, 2002; Ravitz, Maunder, & McBride, 2007; Scharfe, 2007).

There is strong empirical evidence indicating that an individual's interpersonal style is linked to the early learning experiences which include patterns of attachment to caregivers (Horowitz, Rosenberg, & Bartholomew, 1993). According to interpersonal theory (Leary, 1957; Sullivan, 1953), people tend to engage in behaviours which help them to maintain a psychological connection with an earlier attachment figure, even if these, are maladaptive. Individuals are expected to enact interpersonal styles that are close in a representational or literal way to that of their childhood attachment relationships. Despite the likely distress associated with the maladaptive way of relating to others and potential difficulties within social relationships associated with this, it has been suggested that keeping the interpersonal patterns unchallenged avoids a potential increase in anxiety, which can be triggered by relating to others in a different way to the usual, and serves to protect the current self-image.

Interpersonal theories of depression argue that interpersonal factors and mechanisms often maintain depressive symptoms (Coyne, 1976; Lewinsohn, 1974). For example, a person who can be described as having an anxious or ambivalent attachment pattern and abandonment schema can introduce a number of challenges into the relationship by engaging in

behaviours that can be difficult for the other party such as excessive reassurance seeking, proximity seeking, and looking for approval (Mikulincer & Shaver, 2005). Similarly, a person who can be identified as having an avoidant or dismissive attachment pattern and who is often in charge in relationships, might avoid emotional intimacy, acknowledging her/his emotional states, and primarily rely on self (Shallcross, Howland, Bemis, Simpson & Frazier, 2011; Shaver & Mikulincer, 2007). According to Coyne's interactional theory of depression (1976), a person exhibiting depressive symptoms tends to be initially supported by their social network. However, with time, excessive reassurance seeking and ongoing symptoms can lead to a negative affect in others which contributes to a vicious cycle of depressive symptoms. In fact, factors such as excessive reassurance seeking, social isolation, negative emotions, and rejection by other people have been linked to depression (Joiner & Metalsky, 2001; Starr & Davila, 2008).

Interpersonal behaviour has been conceptualised using two dimensions which have been supported by empirical findings. The first, dimension of affection, is captured on an axis representing a continuum of hostile to friendly behaviour, and the second, the dimension of power, is captured on an axis representing a continuum of submissive to dominant behaviour (Millar, Rogers-Millar, & Villard,1978). Importantly, two individuals have a reciprocal impact on each other's behaviour as they interact. In fact, one person's way of acting can invite a particular type of behaviours from the other person. These ways of engaging often compliment each other, i.e. two individuals behaving in a way that can be described as falling at opposing ends of a particular dimension. For example, when person A takes a dominant position in an interaction, person B stays submissive. It is believed that conflict in relationships is more likely when the behaviours of two people fall on the same dimension of an axis e.g. when two people are behaving in a dominant way. The research into interpersonal correlates of PDD is scarce. However, a recent review by Bird, Tarsia and Schwannauer (2018) found a tendency for individuals with PDD to exhibit higher levels of hostile-submissive interpersonal style as opposed to with those with MDD. Importantly, due to a relatively small number of included publications (12) in

the review, secondary analyses using baseline samples of intervention trials with normative data as controls, as well as relatively low overall quality of the studies assessed, more research is required to be able to draw well supported conclusions.

3.2.3. Cognitive-Behavioural Analysis System of Psychotherapy for PD

Cognitive Behavioural Analysis System of Psychotherapy (CBASP) is a psychological intervention designed specifically to treat people who have been suffering from early-onset PDD and who have difficulties with their interpersonal functioning (McCullough, 2003). According to the theoretical model CBASP is based on, PDD, which has an onset before an individual is 21 years of age, is caused by an impairment in cognitive-emotional development and interpersonal functioning caused by experiences of childhood adversity. McCullough explained this impairment in the interpersonal domain using a concept of 'preoperational thinking' studied by Piaget (1981). Piaget noticed that children aged 5-7 function cognitively and emotionally at a preoperational level, which can be further described as egocentric and prelogical. He also observed that when a typically developing child reaches the age of about 7 years old, she/he develops skills that allow for more logical and less egocentrical thinking. McCullough (2003) suggested that children who are traumatised spend all their energy on trying to survive, which limits their opportunities to learn about different ways of experiencing the world, and as a result, affects their interpersonal effectiveness. Such children have been hypothesised to function psychologically at the preoperational level and not be able to understand events from other person's perspective. According to McCullough, functioning at the preoperational level in the interpersonal domain is a risk factor for developing PDD. Importantly, McCullough also suggested that late-onset depression is likely to be caused by an individual's relapse into the preoperational stage, which may be triggered by experiences of particularly stressful events despite a typical childhood.

CBASP was developed in order to address the long-standing maladaptive cognitive-behavioural patterns and interpersonal difficulties found

in the individuals affected by PDD (McCullough, 2000; McCullough 2006). According to McCullough (a view supported by the results of the aforementioned research by Bird et al., 2018), individuals affected by PDD exhibit a hostile-submissive, or socially avoidant, interpersonal style which limits their opportunities for meaningful and rewarding interpersonal experiences. McCullough further argues that PDD is maintained by fears of interpersonal encounters and associated avoidant behaviours which have their origin in past relationship experiences (2006) and result in "disconnection" between a person and his/her environment. Therefore, CBASP was developed to facilitate changes in the patients' interpersonal behaviours, cognitions and affective states which, in turn, are believed to result in a higher awareness of the functionality of their behaviour, increased opportunities to connect to their environment, and an enhanced sense of control. Specific therapeutic techniques involved in CBASP have been developed to help the person move from a socially avoidant/hostile-submissive interpersonal style to a more assertive and friendly one.

While the impact of depression on mental health has been revealed and discussed in extensive research, the mechanisms which lead to, and often perpetuate depressive symptomatology are not very well understood. Gaining a deeper understanding of these mechanisms would allow the therapists to identify the specific areas to target in therapy. Previous research indicated that changes within interpersonal functioning, such as changes within patients' interpersonal styles (as perceived by significant others who did not take part in treatment or by therapists), are related to better outcomes (Constantino et al., 2012; Grosse Holtforth, Altenstein, Ansell, Schneider, & Caspar, 2012). Importantly, even though therapy outcomes usually focus more on reduction in depressive symptoms rather than improvements in social functioning, from a patient's perspective the latter might be more significant. Previous studies found that positive changes within social functioning were seen by patients as one of the three most important factors when considering whether their depression was in remission (Zimmerman et al., 2006), and were seen as a significant treatment goal (Battle et al., 2010). The majority of CBASP sessions involve a situational analysis technique

which helps the patient to address the maladaptive cognitive, behavioural, emotional, and interpersonal responses believed to maintain the depressive symptoms. Completing a situational analysis requires the patient to engage in formal operational thinking in the interpersonal context. It is hoped that through this exercise, patients realise the effect they have on others and their environment, and that their interpersonal style might be a perpetuating factor maintaining their depressive symptoms.

A systematic review has been published discussing evidence from a relatively small number of randomised clinical trials investigating the efficacy of CBASP in PDD (Negt et al., 2016). The authors have reviewed 6 studies involving 1510 patients and studied the effects of CBASP on depressive symptoms. The combined overall effect sizes of CBASP versus other treatments or treatment as usual revealed a significant albeit small effect. Interestingly, moderate-to-high effect sizes were found when CBASP was compared to interpersonal psychotherapy or treatment as usual. CBASP enhanced by antidepressant medication showed better results than the medication itself, which showed similar benefits to CBASP alone. The overall effect sizes observed in the Negt et al.'s review were smaller than those reported by meta-analyses investigating alternative depression treatments. Medium overall effect sizes were found in studies exploring the benefits of CBT (d=0.67, Cuijpers et al., 2010a), IPT (d=0.63; Cuijpers et al., 2011) and short-term psychodynamic therapy (d=0.69; Driessen et al., 2010) on depression.

It seems important to bear in mind that the individuals who participated in the trials reviewed by Negt et al. were affected by chronic, and often treatment resistant, depression rather than by a combination of persistent and episodic depression present in the other reviews. This seems crucial when reflecting on the evidence supporting the effectiveness of CBASP. The Matrix (2015) as well as the most recent NICE guidelines (National Institute for Clinical Excellence, 2017) listed CBASP as the first line of treatment for PDD. NICE guidelines specifically recommended CBASP or CBT in combination with antidepressant medication. While the Matrix graded the quality of evidence supporting the effectiveness of CBASP as 'B' (which requires the evidence to include either well-conducted non randomized clinical studies or

RCT of lower quality demonstrating overall consistency of results), the NICE guidelines assessed several CBASP RCT's as being of 'very low to moderate quality' (the NICE grading system explores, among other things, sample size and risk of bias). It seems that despite the inconsistent quality of evidence and the limited number of studies published in the area, the reviewers are seeing CBASP as a promising treatment in the area of persistent depression due to evidence suggesting small but considerable effect sizes and clinically significant changes in the difficult to treat population.

It is worth noting that despite a different focus of the present systematic review to Negt et al.'s paper, there is a degree of overlap regarding the literature discussed. Four out of six papers included in the systematic review by Negt and colleagues have also been analysed here. Importantly, the main interest of this systematic review were the changes in interpersonal functioning following CBASP therapy, which despite being a crucial factor in patients' wellbeing, were not covered by Negt et al.'s review. As follows, two papers included in Negt et al. review which did not use a measure of interpersonal functioning as part of their design (Kocsis, Gelenberg, Rothbaum, Klein, Trivedi, Manber et al., 2009; Wiersma, Van Schaik, Hoogendorn, Dekker, Van, Schoevers et al., 2014) were excluded from this review.

Taking into account the high prevalence of PDD, its chronic nature and resistance to treatment, as well as its negative impact on psychosocial functioning, it is extremely important to continue research which supports practitioners in establishing the most effective ways of working with patients affected by this condition. While Negt et al. review found evidence to support the efficacy of CBASP, it is worth bearing in mind that the number of the reviewed studies was relatively small, the studies relied on similar methodology affecting the richness of the data, and there was limited data assessing the long-term effects of CBASP. Therefore, it is important to keep reviewing the most up-to-date evidence as further research is being carried out.

3.2.4. Previous reviews

A number of published review studies informed the current review.

Renner, Cuijpers and Huibers (2014) conducted a meta-analysis evaluating studies of psychotherapy for depression that included measures of social functioning. All of the 31 included studies involved a control condition. The findings revealed the impact of psychotherapy on the social functioning of small to moderate effect size with higher quality studies producing lower effect sizes. The changes within the social domain were associated with, but not fully explained by, improvements in depressive symptoms. Importantly, the review investigated the effects of all types of psychotherapy and was not limited to CBASP.

The aforementioned review by Bird et al. (2018) analysed the research measuring the relationship between depression and hostility and/or submissiveness. A meta-analysis was conducted to establish the strength of that relationship. The results have supported McCullough's hypothesis which posits that individuals reporting PDD exhibit a hostile-submissive, or socially avoidant, interpersonal style. The review also established that the individuals with PDD tend to be more hostile-submissive in their interpersonal style as compared to those with episodic depression. Importantly, the review highlighted the limited research in this area and a lack of direct comparison between individuals affected by PDD and episodic depression.

3.2.5. Aim of the current review

This review aimed to evaluate the quality of studies investigating the impact of CBASP on interpersonal functioning in order to assess the validity and reliability of existing empirical evidence in this area. Importantly, both theory and empirical research have acknowledged that adaptive interpersonal functioning is important for many reasons. Firstly, according to the theoretical model described above, challenges in interpersonal functioning can lead to PDD. If this model is correct, resolving difficulties within the social domain of someone's life is likely to lead to a reduction in their depressive symptoms. Treating PDD has been a challenging task and psychological interventions used with this patient group have shown limited benefits. CBASP has been the only therapy developed to specifically treat PDD through addressing interpersonal functioning of the individual. Such a review could help validate the theory behind this particular therapy and justify its implementation with

patients. A better understanding of the benefits of CBASP is likely to impact the treatment delivery, prevention strategies, and wider social policy. Finally, assessing the dropout rates among patients attending CBASP intervention will allow us to draw some conclusions about its feasibility.

3.2.6. Research questions

1) Does CBASP intervention improve interpersonal functioning in individuals affected by PD?

2) Does CBASP intervention reduce depressive symptoms in individuals affected by PD?

3) How confident can we be when drawing conclusions about the effects of CBASP based on the validity and reliability of the existing research?

4) Are CBASP interventions acceptable to participants based on the dropout rates reported by the studies?

3.3. Methods

3.3.1. Registration of protocol

A protocol for the current review was submitted to the PROSPERO international prospective register of systematic reviews (CRD 42019151685). A copy of this protocol can be found in Appendix D.

3.3.2. Search strategy

The following databases were searched from inception, with searches covering up to October 2019: Embase (1980 – October 2019), Medline (1946 to October 2019), PsycInfo (1806 to October 2019), ASSiA (Social Science Premium Collection 1974 to October 2019) and CINAHL Plus (1937 – October 2019). Searches sought to identify studies which reported the effects of a Cognitive Behavioural Analysis Systems of Psychotherapy (CBASP) on interpersonal functioning. Search terms included ("cognitive behavio* Analys*" or "cognitive-behavio* Analys* or CBASP) OR (("chronic* depress*" or "persist* depress*" or "recur* depress*") AND (therap* or intervention*) AND ("cognitive behavio*" or "cognitive-behavio*")). Other appropriate search terms and filters as identified by the individual databases were also included. Reference lists of included studies were scanned for any additional relevant

studies. The leading authors in the area were contacted via e-mail to enquire about additional studies which were not identified by the databases. The search terms were consulted with the Academic Support Librarian at the University of Edinburgh in a meeting during which a number of search strategies were trialled. The search terms were purposefully not overly restrictive due to the limited amount of research in the area. The author decided to look specifically into the area of chronic and recurrent depression as this is the primary mental health diagnosis addressed by CBASP and the one which is included in the aforementioned national guidelines such as the Matrix or NICE under a separate entry.

3.3.3. Inclusion/exclusion criteria

3.3.3.1. Inclusion criteria

Papers investigating the effects of CBASP intervention on interpersonal/social functioning were the focus of this review. The inclusion criteria stipulated that studies had to be published in English and involve a sample of adults (aged 18 and above) with a primary diagnosis of PDD, which was assessed before the intervention has commenced.

For the purpose of the review, PD was defined as having been assessed and found to meet diagnostic criteria for PDD based on DSM-IV. Studies which included clinical samples who were highly likely to be affected by PDD, despite not meeting all of the DSM-IV criteria, were also included. The review included participants affected by:

- chronic/persistent depression i.e. chronic MDD as per DSM-IV; double depression i.e. MDD/MDE as per DSM-IV/V superimposed on dysthymia as per DSM-IV; chronic MDD as per DSM-IV with the modification of at least one year as compared to two years of depressive symptoms; diagnosis of treatment-resistant depression defined as MDD as per DSM-IV/V criteria & lack of response to two trials of ADM's
- recurrent MDD & being at risk of chronic depression: recurrent MDD as per DSM-IV/V with the minimum duration of the current episode six months; recurrent MDD as per DSM-IV/V with incomplete reemission between the episodes as per DSM-IV/V; recurrent MDD with the preceding episode no more than 2.5 years before the onset of the current episode

Interpersonal functioning was defined for the purpose of this review as social interaction and engagement within both intimate relationships and broader interpersonal situations. Included studies had to use a standardised measure or a subscale of a well-established measure of interpersonal functioning or social functioning and report the outcomes using inferential statistics. Both self-reported measures and clinician administered assessments were acceptable.

The included studies had to investigate individual or group CBASP with no minimum or maximum number of sessions. Studies which investigated multiple treatment options were included if one of the treatments offered was CBASP.

3.3.3.2. Exclusion criteria

Studies were excluded if the diagnosis was established using a cut-off score on a measure of depression or if the used samples were non-clinical or the clinical diagnosis was not PD as described above. Studies using qualitative data and single case studies were also excluded. Non-peer reviewed papers including dissertations, book chapters and studies published in a language other than English were also excluded.

3.3.4. Quality rating tool

As this review focused on studies which investigated the effects of CBASP intervention on psychological wellbeing, a quality rating measure that had been designed to assess intervention studies influencing public policy was chosen. The Effective Public Health Practice Project (EPHPP; Thomas, Ciliska, Dobbins, & Micucci, 2004), a quality assessment tool for quantitative studies is a standardised tool which has been developed to ensure the high quality of systematic reviews investigating the evidence which can inform best practice within public health sector. The tool can be used to evaluate different types of intervention studies such as RCT's, before-and-after studies and case control studies. It has been judged to have suitable content and construct validity (Jackson & Waters, 2005; Thomas et al., 2004). EPHPP assists with an overall methodological rating of the studies across eight different domains i.e. selection bias, study design, confounders, blinding, data

collection methods, withdrawals and dropouts, intervention integrity and analysis. The first six of these domains can fall into a strong, moderate or weak category. These categories are then used to provide an overall rating. See Appendix E for the specifics of EPHPP quality rating tool.

3.4. Results

3.4.1. Search results

The initial literature search provided a total of 638 suggested studies (256 from Medline, 115 from Psychinfo, 102 from Embase, 118 from ASSIA, and 47 from CINHAL). An additional record was identified by scanning the reference lists in the relevant articles. Duplicates were removed which resulted in 313 studies. Studies were then further removed if their title had no relevance to the research question (e.g. related to nonhuman subjects, medical interventions, lack of intervention of interest etc.) or if the abstracts made it clear that the inclusion/exclusion criteria were not satisfied. Next, the full publication of the remaining 60 studies was downloaded and screened. After excluding another 52 studies due to a variety of reasons (see Figure 1 below), eight papers were assessed as meeting the eligibility criteria. The vast majority of papers were rejected due to the lack of measure allowing to assess post-therapy changes within the interpersonal functioning among the chronically depressed patients which were the focus of this review. Since this review focused specifically on individuals affected by persistent depression, in order to enhance the evidence base indicating the benefits of CBASP for this population, a couple of studies which looked into disorders other than persistent depression were not included. An additional record was identified by scanning the reference lists in the relevant articles. The details of the search process are presented below as a flowchart (Figure 1).

Nine journal articles published between 2002 and 2018 met the inclusion and exclusion criteria. The included articles were obtained from the journals listed below:

Behaviour Change (N=1);

Biological Psychiatry (N=1);

Depression and Anxiety (N=1);

European Archives of Psychiatry and Clinical Neuroscience (N=1);

Journal of Affective Disorders (N=1);

Journal of Clinical Psychology (N=1);

Journal of Consulting and Clinical Psychology (N=1);

Psychotherapy and Psychosomatics (N=2)

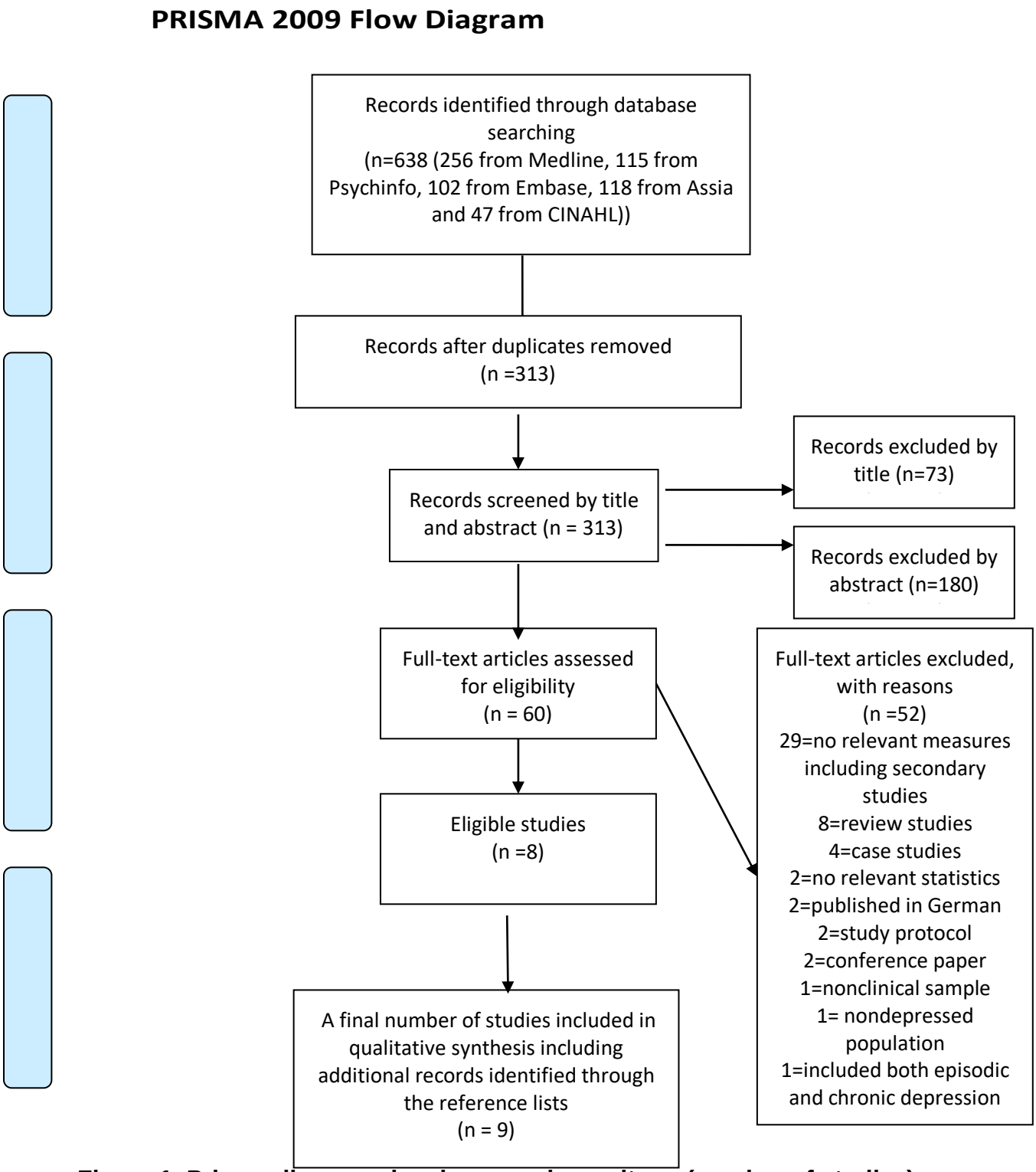

Figure 1. Prisma diagram showing search results; n (number of studies)

3.4.2. Data extraction

Data was extracted from the studies using a tool that was specifically designed for this review. Extraction data included author, year of publication, sample size, average age of participants, sample characteristics/setting, eligibility criteria, design and procedure, main outcome measures, attrition & statistical method, main outcomes, effect sizes and clinical significance, and follow-up data. Table 1 below presents a summary of the reviewed studies.

3.4.2.1. Main outcome measures

The main outcome measures used by the authors of the included studies can be found in Appendix F which includes details of their validity and reliability. The main measures of social functioning used were: the Inventory of Interpersonal Problems (IIP-64/IIP-32; Horowitz, Alden, Wiggins, & Pincus, 2000), the Impact Message Inventory (IMI-C; Kiesler & Schmidt, 2006), the Social Adjustment Scale - Self-Report (SAS-SR; Weissman, 1999), the Social Adaptation Self-Evaluation Scale (SASS; Bosc, Dubini, & Polin, 1997), the Short Form Survey (SF-36; Ware & Sherbourne 1992), and the World Health Organization Quality of Life assessment (WHOQOL-BREF; Group, 1998). The main measures of depression used were: Beck's Depression Inventory (BDI; Beck, Steer, & Brown, 1996), Hamilton Depression Rating Scale (HAM-D/HDRS; Hamilton, 1960), the Inventory of Depressive Symptomatology (IDS-R; Rush, Gullion, Basoo, Jarrett, & Trivedi, 1996), and Montgomery-Asberg Depression Rating Scale (MADRS; Montgomery & Asberg, 1979). The Global Assessment of Functioning measure (GAF; American Psychiatric Association, 1987) as well as the Patient Evaluation Form (PEF; Brakemeier, Strunk, Normann, & Schramm, 2010) were also used to assess the benefits of the intervention.

Table 1
Summary of Studies in Chronological Order

Study	N	Mean Age (SD)	Sample & Criteria	Design	Main Outcome Measures	Attrition & Analyses	Main outcomes	Effect Sizes & Clinical Significance	Follow-Up
1. Hirschfield et al., 2002 (secondary analysis based on study by Keller et al., 2000)	Total (681) CBASP (228) ADM (226) CBASP +ADM (227)	43 (10.7)	Outpatients Diagnosis of MDD (2y+), DD (MDD superimposed on dysthymia), recurrent MDD (depressive symptoms 2y+) as per DSM-IV criteria as well as score ≥ 20 on HAM-D	RCT, Comparison of 3 groups *Intervention 1 CBASP, 1:1, 16-20 sessions* *Intervention 2 ADM* *Intervention 3 CBASP+ ADM* Main DV's : depressive symptoms, social adjustment, social functioning	SAS-SR, social adjustment SF-36, social functioning subscale HAM-D	Dropout & withdrawal from the study: 24% Dropout & withdrawal from CBASP: 24% ANOVA to test pre and post-intervention differences	Significant interaction effects for social adjustment ($F(2,612) = 3.84$, $p < .002$), and social functioning ($F(2,526) = 3.71$, $p < .03$). On SAS, CBASP+ADM superior to ADM, but no difference between CBPASP+ADM and CBASP, no difference between ADM and CBASP. On SF-36 social functioning subscale, CBASP+ADM superior to ADM or CBASP alone, no difference between ADM and CBASP. Keller's et al. (2000) reported improvements on HAM-D across 3 groups, with combination treatment being most effective.	Large ES of CBASP (d=0.97) and CBASP+ADM (d=1.51) on SAS. Large ES of CBASP (d=2.36) and CBASP+ADM (d=3.45) of HAM-D. Psychosocial functioning at the end point, 1SD worse than the community norm	Not reported

2. Schramm et al., 2011	Total (30) CBASP (15) IPT (15)	40.25 (11.7)	Outpatients Diagnosis of MDD (2y+), DD (MDD superimposed on dysthymia), recurrent MDD (depressive symptoms 2y+), dysthymia as per DSM-IV criteria as well as score ≥ 16 on HAM-D Early onset (before 21)	RCT, Comparison of 2 groups *Intervention 1 CBASP, 1:1, 22-24 sessions* *Intervention 2 IPT, 1:1, 22 - 24 sessions* Main DV's : depressive symptoms, social functioning	SASS HDRS BDI GAF	Dropout and withdrawal from the study 13% Dropout and withdrawal from CBASP: 13% ANCOVA (baseline adjustment controlling for pre-treatment scores on all outcome measures) to assess efficacy of treatment At a 12-month follow up, further ANCOVA were used	Lack of main treatment effect on SASS Reduction of depressive symptoms as measured by HDRS in CBASP condition ($t(13) = 3.53$, $p < 0.004$), the effect of IPT on HDRS did not reach a statistical significance, no benefit of CBASP over IPT on HDRS, significant reduction in BDI scores in CBASP group ($t(13) = 5.01$, $p < 0.001$) and in IPT group ($t(14) = 2.34$, $p < 0.034$ Main treatment effect on GAF, both groups improved (CBASP: $t(13) = -3.86$, $p = 0.002$, IPT: $t(14) = -4.45$, $p = .001$).	Large ES of CBASP vs IPT on BDI (d=0.87) Remission rates higher for CBASP vs IPT (CBASP 57% vs IPT 20%)	1 year follow up: 24.1% dropout CBASP group significant changes on SASS Significant changes on BDI for both groups

3. Sayegh et al., 2012	Total (44)	46.75 (8.6)	Outpatients Diagnosis of treatment-resistant depression (MDD as per DSM-IV criteria & failed to respond to two trials of ADM's), average duration of an episode 2 years and 7 months	Cohort study *Intervention: CBASP, 12 group sessions + up to four 1:1 sessions before starting the group* Main DV's: depressive symptoms, social adjustment, interpersonal functioning	SAS-SR IIP-32 BDI	Dropout and withdrawal from the study: 0%, all patients who agreed to participate completed 12 group sessions ANOVA, with pre and post treatment scores as within factor and gender as between-subjects factor	Social adjustment as measured by SAS improved ($F(1,42) = 10.7$, $p \leq .05$) Interpersonal functioning as measured by IIP-32 has not improved Gender did not moderate effects of treatment Symptoms on BDI decreased from severe to moderate level ($F(1,42) = 21.1$, $p \leq .05$)	ES not reported Social adjustment and chronic depression levels did not reach normative levels	Not reported
4. Brakemeier et al., 2015	Total (70)	46.60 (11)	Patients referred by their GP's to the CBASP inpatient programme	Cohort study *Intervention: Inpatient CBASP programme lasting 12*	IMI HAM-D BDI Acceptance	Dropout and withdrawal from the study/CBASP 7.1%	Change on IMI, patients were perceived as more dominant ($b = 0.73$, $SE=1.18$, $p < 0.001$) and friendly ($b = 0.85$, $SE=0.09$, $p < 0.001$). They were also seen as	Large ES of CBASP on HAM-D ($d=2.52$) and BDI ($d=1.15$), dominant interpersonal style ($d=2.08$) and	After 6 months 75% of patients who responded to

			DSM-IV criteria for CD + treatment resistant depression (no response to 2 trials of ADM's and/or no response to 2 trials of psychotherapy with at least 22 session each)	*weeks consisting of 2 1:1 sessions per week, 2 (3 in the main phase) group sessions per week + MDT input* *Outpatient support group offered after discharge.* Main DV'S: depressive symptoms, interpersonal Dynamics	survey	Linear mixed-effect model analysis	less submissive and hostile. Scores on HAM-D decreased (SE = 1.01, p < .001) and on BDI decreased (SE= 1.78, p < .001) 90.4% of the completers found the programme 'helpful' or 'very helpful'	friendly interpersonal style (d=1.69) 75.7% responded to treatment, 40% remitted at post-treatment	CBASP sustained response as measured by HAM-D & BDI, 25% relapsed At 12 months 48% sustained response and 52% relapsed
5. Schramm et al., 2015	Total (60) CBASP (29) ADM/ CM (31)	43.63 (10.56)	Outpatients Chronic MDD as by DSM-IV with the modification of at least 1 year of	RCT *Intervention 1* CBASP, 22 1:1 sessions *Intervention 2 ADM/CM*	SASS MADRS IDS GAF	Dropout and withdrawal from the study: 20% Dropout and withdrawal	Only ADM/CM group improved on SASS between weeks 1-8. No significant main effect or interaction found on SASS between weeks 8-28 Significant Improvement	At 28 weeks: Large ES of CBASP (d=0.98), medium ES of ADM/CM (d=0.50), large ES for ADM/CM+ CBASP (d=1.43) on MADRS	Bausch et al. (2017) follow-up assessment 4.5 years

			depressive symptoms OR recurrent MDD (3 or more episodes with the preceding episode no more than 2.5 years before the onset of the current episode)	*In the case of non improvement after 8 weeks, the other treatment added (either ADM or 12 CBASP sessions)* Main DV's: depressive symptoms, global functioning, social adjustment		from CBASP: 7% Multilevel mixed-effects linear regression analysis, subgroup analyses Baseline MADRS scores as a covariate	in depressive symptoms after 8 weeks as measured by MADRS χ^2 (1) = 12.20, p < 0.001, for both conditions For weeks 8-28, significant improvement for MADRS χ^2 (1) = 50.97, p < 0.001, for both conditions. Improvement also on IDS for both conditions. ADM+CBASP greater improvement between weeks 8-28, χ^2 (2) = 11.22, p < 0.004 than monotherapy All groups improved between weeks 8-28 on GAF	Small ES of CBASP (d=0.32), medium ES for ADM/CM (d=0.23), large for ADM/CM+ CBASP (d=0.54) on IDS Remission: 36.8% in CBASP, 50% in ADM/CM , 30%combined	following the study. 27%dropout Scores on IDS significantly increased CBASP did not result in more sustainable effects than ADM
6. Michalak, Schultze, Heidenreich & Schram, 2015	Total (106) TAU (35) TAU+ CBASP (35) TAU+ MBCT	48.4 (11.5)	Outpatients Diagnosis of chronic MDD as per DSM-IV (2y+), DD (MDE superimposed on dysthymia),	RCT *Intervention 1 TAU (*patients in treatment with a psychiatrist or psychotherapist over the	SASS SF-36, social functioning subscale HAM-D BDI	Dropout and withdrawal from the study: 20% Dropout and withdrawal from CBASP:	No significant effects of CBASP+TAU as compared to TAU on SASS and SF-36. MBCT+TAU different significantly from TAU on SASS measure (Ь=2.43, SE=1.01, p < 0.05)	Medium ES of MBCT on SASS (d=0.57) Large ES of CBASP vs TAU on HAM-D (d=0.82) In CBASP group, 25.7% patients	Not reported

	(36)		recurrent MDD (depressive symptoms 2y+), 88% fulfilled criteria for PDD as per DSM-V criteria	duration of the study) *Intervention 2 CBASP+TAU : TAU + two 1:1 CBASP sessions and 8 group sessions* *Intervention 3 MBCT+TAU: TAU + 8 weekly MBCT group sessions* DV's: depressive symptoms, social adjustment, social functioning		29% Structural Equation Modelling	Decrease in depressive symptoms on HAM-D in all 3 treatment conditions. CBASP+TAU led to a significantly greater decrease on HAM-D than TAU and MBCT+TAU. Decrease in depressive symptoms as measured by BDI in CBASP+ TAU and MBCT + TAU conditions (Ь=-0.24, SE=0.09, p=.01; Ь=-0.23, SE=0.11, p=.04)	remitted, in MBCT 16.7% patients remitted, in TAU group 5.7%	
7. Locke et al., 2017	Total (58) CBASP (36) BA (22)	45.3 (10.4)	Outpatients Diagnosis of MDD as per DSM-IV & at risk of persistent disorder i.e. 82.8% had	RCT *Intervention 1 Group CBASP, two 1:1 sessions + 20 sessions of group*	IIP-32 BDI HDRS	Dropout and withdrawal from the study/CBASP: not reported Multilevel	As measured by IIP, difficulties with assertiveness and agreeableness decreased in CBASP groups (bs= -.094, SEs=.037; bs=-.209, SEs 0.47) but not in BA groups. Other types of	ES and clinical significance not reported	The last post-treatment assessment which was entered

			a previously diagnosed depressive episode (median number of previous episodes:3) the minimum duration of the current episode was 6 months (median duration 24 months)	*CBASP* *Intervention 2 two 1:1 sessions + 20 sessions of group BA* DV's: depressive symptoms, interpersonal functioning		modelling due to patients providing data at different points of treatment and missing data and various time points	interpersonal problems as measured by IIP decreased with time in both groups. Depressive symptoms improved in both conditions, CBASP treatment produced greater improvement than BA treatment (Ь=-5.697, SE=0.688, p≤ .01) as measured by HDRS Self-reported changes in depressive symptoms as measured by BDI, although significant, did not differ between the 2 treatment conditions		into the analysis was carried out 12 weeks after the group has finished
8. Sabaß et al., 2018	Total (116)	45.16 (11.8)	Inpatient setting Diagnosis of CD as per DSM-IV	A naturalistic multicentre feasibility trial, cohort study *Intervention: CBASP treatment: 10 sessions of CBASP group*	WHOQOL-BREF; 4 subscales: physical health, psychological health, social relationships and environment HDRS	Dropout and withdrawal: 10.3% from the study/CBASP paired t-tests to assess changes in	Significant improvement in patients' subjective quality of life as measured by WHOQOL-BREF (t (489) =-5.88, p ≤ 0.001). The improvement was significant across the subscales, including social relationships subscale (p < 0.01).	Large ES of CBASP on HDRS (d=1.48) and on BDI (d=1.11) On HDRS patients improved from moderately to mildly depressed On BDI	Not reported

				therapy DV's: acceptance of the intervention, depressive symptoms, quality of life including social relationships	BDI PEF	outcome measures	As measured by HDRS-24 and BDI, significant improvement over time (t (3226) = 12.71, p ≤ .001; t (386) = 10.40, p ≤ .001). As measured by PEF, patient's acceptance increased over the course of group therapy (t (69) = 6.70, p≤ 0.001, d=0.60). Patients gave CBASP psychotherapy overall mark of 2 (good) on a scale from 1 (very good) to 6 (unsatisfactory). The majority of patients (75.3%) felt that CBASP enriched their overall treatment programme.	depressive symptoms decreased from severe to mild-moderate 33.6% fulfilled criteria for remission	
9. Assman et al., 2018, (secondary analysis based on study by Schramm et al. 2017)	Total (268) CBASP (137) SP (131)	44.9 11.8	Outpatients Diagnosis of early onset MDD of at least 2 years' duration, DD, or recurrent	RCT *Intervention 1 1:1 CBASP, 32 sessions* *Intervention 2 1:1 SP, 32sessions, SP - an*	IIP-64 Comorbidity of AD assessed using Structured Clinical Interview for DSM-IV	Dropout and withdrawal from the study: 14% Dropout & withdrawal from CBASP:12	For IIP-64, significant interaction between the treatment group and AD (F (1,221) = 8.81, p= 0.003). While both treatments produced improvements, patients with AD showed significantly less interpersonal problems	ES of CBASP on IIP for patients with and without AD (d=0.61; d=-0.20) ES of CBASP on HDRS with and without AD (d = 0.79; d=0.12)	Not reported

			MDD with incomplete remission between episodes as defined by DSM-IV	*active, non-specific intervention* DV's: depressive symptoms, global functioning, interpersonal functioning	HDRS	% ANCOVA for measures of depression and interpersonal problems including the main effects of the treatment group and presence of AD as well as the interaction between them	if they were treated with CBASP as opposed to SP Diagnosis of AD had a moderating effect on treatment efficacy, the interaction between the treatment group and AD was significant (F (1, 256) =7.06, p=0.01). While both treatments produced improvement, patients with AD had a significantly lower HDRS score after 20 weeks if they were treated with CBASP rather than with SP.	the remission rate for patients with AD higher in the CBASP group vs SP group (53.7% vs 40.00%)	

Abbreviations: AD (anxiety disorders), ADM (antidepressant medication), BA (Behavioural Activation), CBASP(Cognitive Behavioural Analysis of Psychotherapy), CD (chronic depression), CM (clinical management), DV's (dependent variables), DD (double depression), ES (effect size), IPT (Interpersonal Therapy), MBCT (Mindfulness-Based Cognitive Therapy), MDD (Major Depressive Disorder), MDE (Major Depressive Episode), MDT (multidisciplinary), N (sample size), PDD (Persistent Depressive Disorder), RCT/RT (randomised controlled trial/ randomised trial), SD (standard deviation), SP (supportive therapy),TAU (treatment as usual), W/L (waiting list). Measures: BDI-II (Beck's Depression Inventory; Beck, Steer, & Brown, 1996), GAF (Global Assessment of Functioning; American Psychiatric Association, 1987), HAM-D/HDRS (Hamilton Depression Rating Scale; Hamilton, 1960), IDS (Inventory of Depressive Symptomatology; Rush, Gullion, Basoo, Jarrett, & Trivedi, 1996), IIP (Inventory of Interpersonal Problems; Horowitz, Alden, Wiggins, & Pincus, 2000), IMI-C (Impact Message Inventory; Kiesler & Schmidt, 2006), MADRS (Montgomery-Asberg Depression Rating Scale; Montgomery & Asberg, 1979), PEF (Patient Evaluation Form; Brakemeier, Strunk, Normann, & Schramm, 2010), SAS-SR (Social Adjustment Scale-Self Report; Weissman, 1999), SASS (Social Adaptation Self-Evaluation Scale; Bosc, Dubini, & Polin, 1997), SF-36 (Short Form Survey; Ware & Sherbourne, 1992), WHOQOL-BREF(World Health Organization Quality of Life Assessment; Group, 1998)

3.4.3. Studies published by the same author/authors

Three studies included in the review were published by the same leading author (Schramm et al., 2011; Schramm et al., 2015; Assman et al., 2018 (this was secondary analysis based on study by Schramm et al., 2017)). In the context of limited number of studies which were included in the review, it seems important to discuss potential bias resulting from a phenomenon known as researcher allegiance. Researcher allegiance has been defined as 'the belief in superiority of an intervention and of the superior validity of the theory of change that is associated with the treatment' (Leykin & DeRubeis 2009). Elizabeth Schramm is known for her expertise on CBASP and is a co-author of a book titled 'CBASP as a distinctive treatment for Persistent Depressive Disorder' (McCullough, Schramm, & Penberthy, 2014). It has been suggested that strong commitment to a particular type of therapy might unintentionally affect the results of studies by affecting researcher's judgement, interpretation of the findings or lead to a bias in methodology (Munder, Bruetsch, Leonhart, Gerger, & Barth, 2013). Bearing the risk of researcher allegiance in mind, it is worth noting that the three studies associated with Schramm have been rated as 'strong' and varied in their methodology which resulted in interesting and novel findings.

3.4.4. Conceptualisation of PD

While the above nine studies slightly differed in terms of criteria used to diagnose PD, all of them referred to DSM-IV/DSM-V criteria for MDD, MDE, CD or PDD. Six out of nine studies included participants who had either a diagnosis of MDD, MDD/MDE superimposed on dysthymia, or recurrent MDD with the current symptoms lasting two or more years. One of the studies (Schramm et al., 2015) defined PDD by modifying the standard criterion of depressive symptoms lasting at least two years, and included individuals who were affected by MDD for at least a year, or who reported recurrent MDD (three or more episodes). Although there was no guarantee that this study recruited subjects affected by PDD, the minimum duration of an episode and/or recurrent nature of symptoms made the reported symptoms likely to be either chronic or develop into PDD in the near future. Another study (Brakemeier et al., 2015) used criteria of treatment-resistant depression,

which required a diagnosis of MDD and a lack of response to two trials of ADM's. While the study did not specify a minimum length of an episode, the authors have reported that an average duration of an episode reported by participants was two years and seven months. Given this average duration of an episode and the time that is usually required to diagnose a person with MDD and implement two trials of medication, it was assumed that the episodes were likely to be of chronic nature. In the study by Locke et al. (2017), participants had to have a diagnosis of MDD with a minimum duration of an episode set at six months and be at risk of PDD i.e. 82.8% had a previously diagnosed depressive episode (median number of previous episodes: three).

3.4.5. Methodological evaluation

Each of the nine articles were read multiple times and were subsequently assessed using the EPHPP evaluation tool (Thomas et al., 2004) by the first author. A fellow doctoral trainee was then asked to review five out of nine studies (55.5%) in order to establish the quality of the assessment. Inter-rater agreement was found to be excellent with Cohen's kappa of 97% (Cohen, 1960) which was in line with the research findings suggesting fair to excellent agreement between raters across different domains of EPHP (Armijo-Olivo, Stiles, Hagen, Biondo, Cummings, 2012). The disagreements with the independent rater were relatively easy to resolve through a discussion as they focused on the psychometric properties of the measures used in the studies, which while well established in the literature, were unclear to the independent rater due to lack of clarity in the reporting. A summary of the EPHPP quality ratings can be found in Table 2 below. The following section further discusses the results of the EPHPP evaluation for the nine intervention outcome studies. The areas of evaluation discussed will be in accordance with the sections and sub-sections of the EPHPP.

Table 2
Summary of the EPHPP evaluation with additional information regarding the use of statistics

Study	Selection Bias Risk	Study Design	Confounders	Blinding	Data Collection	Withdrawals & Dropouts	Intervention Integrity	Statistical Analysis	Intention to Treat Analysis	Power	Global Rating
1. Hirschfield et al., 2002	moderate	strong	strong	moderate	moderate	moderate	moderate	appropriate	yes	not reported	**strong**
2. Schramm et al., 2011	moderate	strong	strong	moderate	moderate	strong	strong	appropriate	yes	underpowered	**strong**
3. Sayegh et al., 2012	moderate	moderate	strong	weak	strong	strong	strong	appropriate	no dropouts	not reported	**moderate**
4. Brakemeier et al., 2015	moderate	moderate	strong	weak	moderate	strong	strong	appropriate	yes	not reported	**moderate**
5.Schramm et al., 2015	moderate	strong	strong	moderate	strong	strong	strong	appropriate	yes	underpowered	**strong**
6. Michalak et al. 2015	moderate	strong	strong	moderate	moderate	moderate	moderate	appropriate	yes	underpowered	**strong**
7. Locke et al., 2017	moderate	strong	weak	moderate	moderate	weak	weak	appropriate	not reported	not reported	**weak**
8. Sabaß et al., 2018	moderate	moderate	strong	weak	moderate	strong	weak	appropriate	yes	not reported	**moderate**
9. Assman et al., 2018	moderate	strong	strong	moderate	moderate	strong	strong	appropriate	yes	underpowered	**strong**

Measures: EPHPP (The Effective Public Health Practice Project; Thomas, Ciliska, Dobbins, & Micucci, 2004)

3.4.6. Risk of selection bias

In order to recruit participants to the studies, the authors relied on opportunity sampling. They either invited individuals who were known to be affected by depression in outpatient or inpatient settings to take part in the study or advertised the study in the community. The main difficulty with opportunity sampling is that the sample is not randomly selected, and therefore, it is likely to be biased. Furthermore, such samples often represent very specific populations (community members or patients who are motivated and well enough to participate) which might not be highly representative of the population affected by PDD as a whole. In addition, no study reported how many of the approached individuals or the individuals who expressed an initial interest consented to take part in the study. For the above reasons, all nine studies were rated as 'moderate' on the item assessing risk of selection bias.

3.4.7. Study design

Although RCT's are the gold standard for exploring causal relationships between interventions and outcomes, only six out of the nine evaluated studies both used a control/comparison group and randomised participants into different conditions. The studies were rated as 'strong' on the study design item. The other three studies, which used cohort design comparing the same group of subjects before and after the intervention, were rated as 'moderate'. Importantly, the process of randomisation which balances participants' characteristics between the groups helps to reduce bias when examining cause and effect relationships. The RCT design allows a greater degree of certainty when drawing conclusions about the outcomes of the interventions by allowing attribution of any changes within outcomes to the actual intervention. Importantly, out of the six RCT studies, four used TAU/SP/IPT/MBCT/BA interventions and two ADM as comparison conditions. Designing a study with an appropriate control group can be particularly challenging for studies involving participants with a mental health condition. Withdrawing or delaying treatment can be seen as unethical and it is also likely to lead to a higher dropout among the subjects. Nevertheless, the lack of appropriate control condition makes the interpretation of the results more

difficult due to potential confounding variables that might be influencing the outcomes e.g. talking to a therapist.

3.4.8. Confounders

Overall, attempts made by authors to control for confounding variables (which the EPHPP defines as differences between groups pre-intervention) which can be seen as a potential threat to the study validity were assessed as 'strong', except for one study which did not report a baseline comparison between treatment groups on standard demographic variables and for that reason was assessed as weak. The majority of the studies run analyses comparing participants across conditions on characteristics such as age, gender, marital status, employment and education history. Some studies also included additional variables such as severity of depression, comorbidities, medication intake, and psychotherapy attendance. Importantly, the majority of analyses showed no differences between the groups on tested variables. If differences were found, they were controlled for using statistical methods. For the two studies which used a cohort design with one study condition, the problems associated with between-groups differences were not relevant.

3.4.9. Blinding

Six out of nine studies ensured that the outcome measures were collected by a member of the research team who was unaware of the condition the participant was allocated to. However, due to the fact that it is impossible to blind therapists to the intervention they deliver and fully blind the subjects as to what condition they participate in, these six studies were rated as 'moderate' on the 'blinding' item. The remaining three studies were cohort studies and by the virtue of their design blinding was difficult, and therefore they were rated as 'weak'.

3.4.10. Data collection method

Both reliability and validity of the used measures were judged as 'strong' for only two out of nine studies. The main questionnaires used by these authors are well-established and have strong psychometric properties (see Appendix G). Seven studies which incorporated the HAM-D/HRSD,

clinician-administered measure, were assessed as 'moderate' due to research indicating poor psychometric properties of this particular scale. However, it is also worth bearing in mind that most outcome scores were assessed using self-report measures only, and therefore the clinician-administered scales such as HAM-D, IMI and GAF can be a valuable source of data. It would have been useful if the authors of each study used reliable and valid clinician-administered measures or interviewed the participants to increase accuracy of the assessment.

Importantly, evaluated studies used a number of different measures to assess variables of interest. In order to assess depression, seven studies have used HAM-D/HRSD, six studies used BDI, and one study used MADRS and IDS. In order to assess interpersonal functioning/social functioning, three studies used IIP measuring interpersonal problems, three studies used SAAS measuring social adaptation, two studies used SAS-SR measuring social adjustment, and one study used clinician-rated IMI measuring interpersonal style. Two studies used social functioning subscale of SF-36 and one study used social relationships subscale of WHOQL-BREF. The use of different subscales makes it more difficult to compare the results across the studies as there is no certainty that the studies are indeed evaluating the same conceptual constructs. It is also worth remembering that the psychometric properties of the measures are often based on the full scale, and therefore, in order to increase reliability and validity of the findings, it may be more useful to rely on the full scale rather than a subscale of a measure that was designed to capture a wider concept.

3.4.11. Withdrawals and dropouts

The majority of the studies have reported the rate of withdrawals and dropouts after assigning participants to the study condition. The rate of withdrawal and dropouts was well documented and relatively low (less than 20%) for six studies which were assigned a 'strong' rating. Two studies reported significantly higher withdrawal and dropout rates (more than 20%) which led to a 'moderate' rating. One study did not report on this item, and therefore received a 'weak' rating**.** Without information on dropout rates, it can be difficult to assess how biased the final sample was.

The drop-out rate in CBASP conditions was calculated to be between 0% and 29% with an average rate of approx. 12% (14% at the level of a study). Such dropout rates are seen as not unusual when compared to other studies assessing the effects of a therapeutic intervention, indicating that the CBASP intervention is indeed feasible. In fact, a meta-analysis of dropout rates in studies involving outpatient psychotherapy for MDD revealed an average rate of discontinuation of 19.9% (Cooper & Conklin, 2015). Higher dropout rates were reported to be associated with comorbid personality disorders or a minority racial status which might also be a potential explanation behind the heterogeneity of the dropout rates among the studies in this review.

Importantly, the unequal loss of participants in clinical studies can lead to attrition bias. Participants can withdraw for a variety of reasons or they might be excluded due to, for example, the violation of the study protocol. Such drop-outs can affect the power of the study and lead to the differences between the groups. To overcome the attrition bias and as a way of dealing with missing data, intention to treat analysis (ITT) has been introduced as part of the statistical computations (McCoy, 2017). Intention to treat analysis allows all the patients who were randomised into the trial to be included in the final analysis. As part of ITT end-point values need to be estimated of the lost patients or data points. A number of approaches have been developed to estimate these data including ‘last observation carried forward’ analysis and multiple imputation. Seven out of nine studies have used either of these techniques. The remaining two studies (Locke et al., 2007; Sayegh et al., 2012) did not report on how they handled attrition or missing data.

3.4.12. Overall ratings

The overall ratings assigned to each study are based on the above six quality rating items. To summarise, five studies have been assigned a 'strong' rating, three studies have been assigned a 'moderate' rating and one study was assessed as 'weak'.

3.4.13. Additional evaluations

There are two additional rating items on the EPHPP i.e. integrity of the intervention and statistical analysis which do not contribute to the overall evaluation and do not have an official rating scale, but can be seen as equally important when assessing the validity of the study, and therefore have been assessed by the author of this review.

3.4.14. Integrity of the intervention

The majority of the studies (five out of nine) were rated as 'strong' on this item as they reported a method of measuring the consistency of the intervention delivered and the dropouts within the condition delivering the intervention of interest were under 20%. Two studies have been rated as 'moderate' due to a relatively high dropout rate. One of the studies did not report on the method of ensuring consistency, and despite acceptable dropout rates, was rated as 'weak'. Another study which was rated as 'weak' did not report the dropout rates at all. While there was no evidence of an 'unintended intervention' that might have influenced the results, only the studies with an appropriate control group can claim with a high degree of certainty that it was, in fact, CBASP intervention that has led to the changes in the measured outcomes.

3.4.15. Statistical analysis

The studies have been assessed as using appropriate and well-justified statistical analyses. However, the validity of the analyses was threatened across the studies due to insufficient power or power not being reported. It is worth remembering that a small sample can increase the chance of type II error resulting in significant outcomes not being detected due to low statistical power. The presentation of test results across the studies was acceptable, with the majority of the studies reporting t/F values, p values and degrees of freedom. It is worth noting that seven out of nine studies reported effect sizes for the main outcomes which were most often related to the depressive symptomatology.

3.4.16. Outcomes

Does CBASP intervention improve interpersonal functioning in individuals affected by PD?

Does CBASP intervention reduce depressive symptoms in individuals affected by PD?

Are CBASP interventions acceptable to participants based on the dropout rates reported by the studies?

Please see the Table 3 below which summarises the main outcomes for each of the studies.

Table 3
Brief summary of outcomes

Study	Depression Diagnosis	Comparison	Primary Outcome-Social Functioning	Primary Outcome-Depression	Changes in Social Functioning	Changes in Depression	Therapy Format	Sessions
Hirschfield et al., 2002	Chronic	ADM CBASP+ADM	SAS-SR Subscale of SF-36	HAM-D	Improved	Combination treatment most effective	1:1	16 - 20
Schramm et al., 2011	Chronic	IPT	SASS	HDRS BDI	lack of effect	Improvement in CBASP; no benefit of CBASP over IPT	1:1	22 - 24
Sayegh et al., 2012	Chronic	n/a	SAS-SR IIP-32	BDI	improvement on SAS-SR, not on IIP	Improved	Group+ 1:1	12 + up to 4 x 1:1
Brakemeier et al., 2015	Chronic	n/a	IMI	HAM-D BDI	Improved	Improved	Group+ 1:1 + MDT input	24+, exact no unclear
Schramm et al., 2015	Chronic or Recurrent	ADM/CM	SASS	MADRS IDRS	Only ADM/CM group improved	Combination treatment most effective	1:1	22
Michalak et al., 2015*	Chronic	TAU MBCT+TAU	SASS Subscale of SF-36	HAM-D BDI	Only MBCT group improved on SASS, no effect on SF-36	Improved, benefit of CBASP over MBCT on HAM-D	Group+ 1:1	8 (plus 2 x 1:1 in CBASP)
Locke et al., 2017	Recurrent	BA	IIP-32	HDRS BDI	Benefit of CBASP over BA on some subscales	Improved, benefit of CBASP over BA on HRSD	Group+ 1:1	22
Sabaß et al., 2018	Chronic	n/a	Subscale of WHOQOL	HDRS BDI	Improved	Improved	Group	10
Assman et al., 2018	Chronic or Recurrent	SP	IIP-64	HDRS	Benefit of CBASP over SP for patients with comorbid AD	Benefit of CBASP over SP for patients with comorbid AD	1:1	32

Notes: CBASP was the intervention delivered in all studies, in the study marked * CBASP + TAU was used; *Abbreviations:* AD (anxiety disorders), ADM (antidepressant medication), BA (Behavioural Activation), CBASP(Cognitive Behavioural Analysis of Psychotherapy), CM (clinical management), IPT

(Interpersonal Therapy), MBCT (Mindfulness-Based Cognitive Therapy),n/a (not applicable), MDT (multidisciplinary), SP (supportive therapy),TAU (treatment as usual); Measures: BDI-II (Beck's Depression Inventory; Beck, Steer, & Brown, 1996), HAM-D/HDRS (Hamilton Depression Rating Scale; Hamilton, 1960), IIP (Inventory of Interpersonal Problems; Horowitz, Alden, Wiggins, & Pincus, 2000), IMI-C (Impact Message Inventory; Kiesler & Schmidt, 2006), SAS-SR (Social Adjustment Scale-Self Report; Weissman, 1999), SASS (Social Adaptation Self-Evaluation Scale; Bosc, Dubini, & Polin, 1997), SF-36 (Short Form Survey; Ware & Sherbourne, 1992),

3.4.16.1. CBASP and outcomes on interpersonal/social functioning

Six out of nine studies revealed a significant effect of CBASP intervention on at least one of the measures assessing interpersonal/social functioning they used. Two studies (Assman et al., 2018; Locke et al., 2017) found a significant improvement on interpersonal functioning as measured by IIP. Two studies (Hirschfield et al., 2002; Sayegh et al., 2012) reported a significant effect of CBASP on social adjustment measured by SAS. Additionally, a study by Hirschfield et al. (2002) found an improvement on social functioning measured by SF-36. A study by Brakemeier et al. (2015) found patients to be more dominant and friendly following the intervention as shown by the IMI. There was a significant change within social relationships as measured by a subscale of the WHOQOL questionnaire used by Sabaß et al. (2018).

Three studies (Michalak et al., 2015; Schramm, 2011; Schramm et al., 2015) which used SASS as an outcome measure found no change, suggesting either the lack of improvement in the areas of social functioning, or that this particular questionnaire did not capture the processes targeted by CBASP. One of the studies (Michalak et al., 2015) which used SF-36 alongside SAAS found lack of improvement on both of the measures.

A number of studies compared the effects of CBASP with an alternative intervention. A study by Hirschfield et al. (2002) revealed a benefit of a combined intervention (CBASP + ADM) over medication on both SF-36 and SAS measures. A study by Locke et al. (2017) revealed the benefit of CBASP over BA on some but not all aspects measured by IIP (an increase in assertiveness and a decrease in agreeableness). In the study by Assman and colleagues (2018) patients treated by CBASP as opposed to SP have experienced more positive changes within interpersonal functioning only if they had a comorbid diagnosis of AD. Importantly, Schramm et al. (2011) and Michalak et al.(2015) failed to demonstrate the effects of CBASP on the interpersonal/social outcomes, or its superiority over IPT or MBCT respectively. In fact, MBCT led to a significant change on the SASS measure as compared to CBASP intervention which had no effect.

It has become standard practice to determine effect sizes when reporting the results of the intervention (Kirk, 1996). Effect size indicates the

magnitude of the difference between the groups. Three out of nine studies reported effect sizes (see Table 1) , which ranged from small to large, illustrating the magnitude of the change within the interpersonal functioning following CBASP intervention as assessed by three different measures (IIP, SAS and IMI).

Importantly, the two studies which assessed the clinical significance of the changes observed within the interpersonal domain following the CBASP intervention reported that the levels of social functioning post-treatment were still significantly higher compared to those of the normative samples. Hirschfield and colleagues (2002) reported that psychosocial functioning at the end point was one standard deviation worse than the community norm. The process of establishing clinical significance requires the use of reliable measures that are indicative of norms for a typically functioning population, and thus can be challenging. Nevertheless, it is of great importance to do so as determining clinical significance enhances credibility of the observed effects and is indicative of the magnitude of the effect the intervention had on the participants' daily life.

Six different measures were used to assess aspects of interpersonal/social functioning (IIP, SAAS, SAS, IMI, and subscales of SF and WHOQOL). It is possible that a considerable variance between the measures used yielded different results due to them assessing a range of different concepts. For example, the IIP assesses a number of aspects associated with interpersonal functioning such as sociability, assertiveness, aggression, supportiveness, involvement, caring, openness and dependency. CBASP aims to increase patients' understanding of the functionality of their behaviours and sense of control. Specific techniques in CBASP also help the person to move from the socially avoidant/hostile submissive position towards a more assertive and friendly one. Therefore, one might expect the changes within the areas measured by the IIP. In fact, two out of three studies which have used the IIP as a measure found an improvement within interpersonal functioning following CBASP intervention. In contrast, three studies which used SASS, a scale which is used to assess social motivation and behaviour in depression, have not revealed any effects of CBASP on interpersonal functioning.

3.4.16.2. CBASP and outcomes on depression measures

All of the nine studies revealed a significant effect of CBASP intervention on depressive symptoms as assessed by both self-report and clinician-administered measures. The preliminary evidence from three studies (Locke et al, 2015; Michalak et al., 2015; Schramm et al., 2011) indicated the benefit of CBASP over alternative interventions recommended for depression such as IPT, MBCT and BA. It is worth noting that the benefit of CBASP as compared to MBCT was demonstrated on HAM-D but not BDI measure. The study by Hirschfield et al. (2002) and Schramm et al. (2015) demonstrated that the combined treatment of CBASP and ADM was superior to CBASP alone on measures of depression. Study by Assman et al. (2018) found CBASP to be more effective in reducing depressive symptoms when treating patients with comorbid AD. Seven out of nine studies reported effect sizes of CBASP on depressive symptoms which ranged from small to large. In order to assess the clinical significance of the observed changes within the depressive symptomatology, six out nine studies reported remission rates, which in CBASP conditions oscillated between 25.7% and 57%.

3.4.16.3. Outcomes at follow-up

Outcomes at follow-up were reported by three studies only and were inconsistent. Two studies (Brakemeier et al., 2015; Schramm et al., 2011) have reported follow-up results at 1 year and one study (Bausch et al., 2017) at four and a half years post-treatment, with only one of these studies including a measure of social functioning. While Schramm et al. (2011) have shown that the effects of CBASP on depression and social functioning were maintained, Brakemeier et al. (2015) have shown that slightly more than a half of completers (52%) relapsed, with the remaining 48% sustaining a response to treatment as measured by changes within depressive symptoms. Finally, a study by Schramm et al. (2015) revealed a significant increase in reported depressive symptoms.

It is worth noting that such results suggesting that roughly half of the patients report long-lasting effects of the treatment are not unusual. While several studies indicated the medium-term effectiveness (6months-1year) of

CBT for depression (Hollon et al., 2005; Kovacs, Rush, Beck, & Hollon, 1981; Miller, Norman, & Keitner, 1989), the sample sizes included in the studies were often relatively small (75 per treatment condition) which limited the generalizability of the findings. A large trial on the effectiveness of CBT delivered alongside usual care (that included antidepressants) on treatment resistant depression carried out in 2013 by Wiles and colleagues (2012), involved 469 patients with 235 patients being assigned to treatment as usual and 234 patients to CBT plus treatment as usual. Ninety percent of the patients were followed up at 6 months and 84% at 12 months. The authors have found that 46% of the patient in the CBT group met criteria for response (50% reduction in depressive symptoms) at 6 months as compared to 22% of patients in the treatment as usual group. The benefits were maintained at 12 months.

3.4.16.4. Delivery of CBASP

Across the studies, CBASP intervention was delivered in different ways using manuals for individual therapy, group therapy and a specific CBASP programme within an inpatient setting. Four out of nine studies delivered CBASP in a 1:1 setting with a number of sessions ranging from 16 to 32. Four studies delivered CBASP in a group setting with the number of sessions ranging from eight to 20. Three out of these four studies offered participants between two to four individual sessions prior to starting the group in order to work out a transference hypothesis which is part of CBASP treatment. One study delivered an inpatient programme consisting of a combination of individual, group and an multidisciplinary input, and did not report the exact number of sessions provided. It is worth pointing out that while there does not seem to be a pattern suggesting that one way of delivery is more beneficial than the other, more studies exploring the effects of CBASP are needed to be able to make valid comparisons.

3.5. Discussion

3.5.1. Summary of findings

The present review focused on improvements in the area of social functioning, showing promising results. The majority of the reviewed studies

have revealed the improvements on the measures of interpersonal functioning, and all of the studies reported improvements in depressive symptoms following the CBASP intervention. Only six out of the nine reviewed studies used an alternative intervention as a comparison group to CBASP condition. Due to the small number of studies and mixed results, the findings with regards to the effectiveness of CBASP as compared to alternative interventions are somewhat inconclusive.

The changes in depressive symptoms following CBASP intervention found in this review are in line with the findings from a meta-analysis by Negt et al. (2016) adding to the evidence indicating that CBASP is effective in treating PD. While the reduction in depressive symptoms took place across all of the studies, only six out of nine papers have revealed positive outcomes in the area of interpersonal functioning. Importantly, there was a high degree of variation in how interpersonal functioning was defined and measured across the studies making the findings difficult to compare. It is possible that while CBASP improves aspects of interpersonal functioning such as assertiveness or dependency measured by IIP, it does not have an immediate impact on the broader social functioning associated with work, home life, friends and hobbies, as measured by SASS, which might take more time to change. Interestingly, the study by Weissman, Olfson, Gameroff, Feder, & Fuentes (2001) which compared the SF-36, SASS and SAS revealed that while the scales were able to differentiate between clinical and non-clinical populations, there was only modest correlation between them suggesting that they might be measuring slightly different concepts. It might be helpful in the future to use multiple well-established scales in the same study in order to assess the exact aspects of social functioning that change as a result of CBASP intervention.

A more consistent approach was visible regarding the assessment of depressive symptoms, perhaps due to the relative clarity of the definition of depression. Six out of nine studies used BDI as a measure of depression, with the remaining studies using either clinician-administered outcome measures or alternative self-report measures (e.g. IDS). The use of measures assessing similar, if not the same, concepts allowed the researchers to demonstrate the improvements in the specific symptoms of depression across the studies.

Research findings suggest that individuals with severe interpersonal difficulties can be more reluctant to change (Borkovec, Newman, Pincus, & Lytle, 2002; Gurtman, 1996; 2002; Muran, Segal, Samstag, & Crawford, 1994). Difficulties with being assertive and not attending to one's own needs have also been found to correlate with higher levels of depressive symptoms post-treatment (McEvoy et al., 2013) and are associated with poorer treatment outcomes in subjects with generalised anxiety disorder (Borkovec et al., 2002) and depression (Hardy et al., 2001). It is possible that participants included in the studies which showed no improvement in interpersonal or social functioning were affected by particularly severe interpersonal difficulties.

Interestingly, a study by Assman et al. (2018) indicated that CBASP treatment might be particularly useful for chronically depressed individuals who suffer from comorbid AD. The authors found that CBASP was superior to SP only for those participants who reported anxiety alongside depression. Furhter analysis showed that the superiority of CBASP over SP was demonstrated only for the individuals struggling primarily with social anxiety. It is possible that even though CBASP was developed specifically for chronic depression, the techniques it uses help to target a number of transdiagnostic psychological mechanisms which are likely to be implicated in a number of other disorders including social anxiety (Rodebaugh, Holaway, & Heimberg, 2004). For example, CBASP aims to increase one's awareness of the effects the individual's behaviours have on others, with the hope that this will lead to an increase in satisfactory relationships. A person who has learned to pay more attention to particular aspects of the interactions as they happen, might also be less likely to ruminate on their negative thoughts, which in turn can lead to a reduction in anxiety.

Importantly, the dropout rates for the included studies indicated that CBASP is an intervention that is acceptable to patients. Furthermore, 90.4% of the completers in the study by Brakemeier et al. (2015) found the intervention 'helpful' or 'very helpful', while the study by Sabaß et al. (2018) revealed that, on average, the patients rated the group version of the intervention in the inpatient setting as 'good'. Five out of nine included studies have designed their interventions to be viable in group settings. It is worth pointing out that stepped care models of service delivery recommended by the

National Institute for Health and Care Excellence (2011) encourage access to lower intensity psychological interventions, such as cognitive-behavioural groups, as they can often reach a large audience at a lower cost. Indeed, CBASP lends itself very well to a group setting given the interpersonal focus of the intervention. In a group setting, positive and negative reinforcements can be provided by peers and reflected on with the guidance from the facilitator. Group therapy for depression has been shown to be equivalent or marginally less effective (only in short-term) when compared to individual therapy (Cuijpers, Van Straten, & Warmerdam, 2008) while its cost has been shown to be less than half of that of one-to-one therapy (Vos, Corry, Haby, Carter, & Andrews, 2005). Group settings might also be particularly useful when developing post-treatment continuation and maintenance support groups aimed at treatment resistant depression or reducing the likelihood of relapse. Research comparing individual and group interventions could help services to choose the most suitable modes of therapy that meet patients' needs. Further research into the effects of individual and group CBASP on patient's mental health is likely to contribute to more cost effective and refined interventions for PD.

Only two out of nine reviewed studies (Schramm et al., 2011; Brakemeier et al., 2015) have reported follow-up results and only one of them included a measure of social functioning at that stage. The findings were mixed, suggesting that a significant number of patients might relapse a year after the intervention. Due to the lack of substantial data, these findings should be interpreted with caution. It has been suggested before, that in order to maintain the benefits of therapy for chronic depression, long-term courses of psychological intervention might be helpful (Conradi et al., 2007; Cuijpers et al., 2010b).

It is also worth noting that the present review focused on the individuals affected by PDD i.e. the population CBASP was specifically developed for. In the light of new evidence, suggesting that CBASP may be effective when used as a preventative intervention or trauma intervention (Braithwaite, Scott, Fincham & Frank, 2000; Favorite, Messina, Smith, & Porcari), it could be helpful to review the evidence with other clinical and non-clinical populations.

3.5.2. Quality of evidence

How confident can we be when drawing conclusions about the effects of CBASP based on the validity and reliability of the existing research?

Although the findings from this review provide preliminary evidence for the effectiveness of CBASP on interpersonal functioning and depressive symptoms, validity and reliability of the results can be seen as somewhat limited.

In terms of the methodological quality, the studies under investigation have been shown to be of a good standard with an overall strong or moderate rating assigned to eight out of nine studies. Only one study received a weak rating; it was also the only study that did not report dropout and withdrawal rates. The majority of the studies adopted randomised designs, used cohorts that can be seen as, overall, representative of the patients in the healthcare system, and used appropriate data collection methods with suitable statistical analyses. A good methodological quality across the studies ensured reliability and validity of the results. Nonetheless, a number of limitations to the current body of research investigating the effects of CBASP on interpersonal functioning and depression have been uncovered in this review.

Only six of the above studies have been designed as RCT's with TAU (or an alternative intervention) acting as a control/comparison group. The lack of a suitable comparison group in the majority of the studies introduces a number of questions with the regards to the mechanisms of change that were responsible for the positive outcomes. It cannot be stated with confidence that the changes within depressive symptoms and interpersonal functioning were a result of CBASP as opposed to nonspecific psychosocial ingredients of other interventions. The two studies which compared CBASP to non-specific intervention (TAU and SP) produced inconsistent results which makes the interpretations of the findings difficult.

Somewhat surprisingly, none of the studies demonstrated sufficient power which threatened the overall validity of the analyses. Four studies were underpowered with the remaining five neglecting to discuss this issue. It is possible that the effects of CBASP on interpersonal functioning have not been

detected in three out of nine studies simply due to the insufficient number of participants. While difficulties with recruitment of depressed patients have been documented in the past (Hughes-Morley, Young, Waheed, Small, & Bower, 2015), it is essential for the researchers to calculate required sample size a priori and aim to recruit enough participants to be able to increase the validity of supported hypotheses.

Another variation between the studies, which made comparisons more difficult, were the differences between treatment protocols. Five of the studies reported delivering CBASP in a group setting which has proven to be a popular approach in the healthcare services as it maximises the number of patients that can be seen at any one given time. However, due to the somewhat inconsistent methods of treatment delivery and a substantial variation in the number of sessions delivered in each study (with the number of sessions available to the patient ranging from 8 to 32), it is likely that the differences between the outcomes across the studies can be partially explained by the variation in the treatments offered to patients. It has been found that at least 18 sessions are required for patients with PDD in order for them to benefit from the optimal effects of psychological intervention (Cuijpers et al., 2010b). Research has also shown that the initial stage of CBASP therapy may in fact lead to a deterioration, given the often traumatic nature of the experiences discussed (Brakemeier et al., 2015). Indeed, study by Michalak et al. (2015), which showed no benefit of CBASP over TAU, included only 10 sessions of CBASP, out of which only the first two were offered on one to one basis.

3.5.3. Limitation of the current review and implications for the future research

This review has a number of limitations. Due to a relatively small number of studies investigating CBASP intervention (as compared to, for example, CBT), and even fewer using measures of interpersonal functioning while investigating the population affected by PDD, these findings have to be interpreted with a degree of caution in terms of their generalisability. Furthermore, all of the included studies relied on similar qualitative methodology limiting the richness of data it produced. Hopefully, future studies

investigating interpersonal functioning and associated mechanisms of change will employ more varied designs including, for example, qualitative methods of data collection. It is also worth bearing in mind that research which shows the significant effects of clinical interventions is more likely to be published in scientific journals (Hemingway & Brereton, 2009) which might have led to publication bias.

It seems that while empirical base supporting CBASP as an intervention for PD is growing, the specific mechanisms of change have not been fully explained. Given McCullough's theory suggesting the mediating role of cognitive-emotional development and interpersonal functioning between trauma and PD, more researchers should focus on investigating these two factors. In fact, it is somewhat surprising that only nine articles have met the inclusion criteria for this review. In the future, it would have been useful for CBASP studies to include IIP measure as a standard assessment of interpersonal functioning alongside other measures assessing different aspects of this broad construct. Being able to form and develop interpersonal relationships has been discussed as the cornerstone of happiness and wellbeing while difficulties in this area have been found to be associated not only with depression but also with anxiety, eating disorders and personality disorders. Future research should continue to study different aspects on interpersonal functioning to establish the exact factors that can contribute or lead to a reduction in the above difficulties. Learning about specific aspects of interpersonal functioning and their impact on depressive symptoms could help clinicians set specific goals when planning an intervention.

The current review has indicated that CBASP intervention tends to improve the aspects of interpersonal functioning which are targeted by CBASP techniques while also reducing depressive symptoms. Somewhat surprisingly, the literature search revealed that the vast majority of CBASP studies did not include measures of interpersonal functioning. Due to the small amount of studies included in this review and a number of methodological differences between them, more research in this area is necessary to be able to interpret the findings with confidence. It would be useful if future studies focused more on the specific mechanisms of change involved in CBASP

which would hopefully provide us with insight into the treatment of depression and, perhaps, other clinical conditions.

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4. Chapter 2: Empirical study

The use of multiple regression analysis as a test of Behavioural Analysis System of Psychotherapy (CBASP) model of persistent depression

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4.1. Abstract

Background. McCullough's theory of persistent depression (2000) posits that childhood trauma leads to an impairment in the area of cognitive-emotional functioning, which causes difficulties in the interpersonal functioning, which then can cause depression. However, only a few studies to date have sought to establish the evidence for this theoretical model.

Methods. Thirty-two patients completed and returned a questionnaire pack assessing childhood trauma, pre-operational thinking, reflective functioning, interpersonal difficulties and depression. A series of multiple regression analyses were used to assess the results.

Results. No association was found between childhood adversity and the severity of depression. Childhood adversity, pre-operational thinking and interpersonal difficulties did not predict the severity of depressive symptoms. Furthermore, no association was found between childhood adversity and interpersonal functioning, or between interpersonal functioning and depression. The relationship remained not significant even when a subscale of the Inventory of Interpersonal Problems was used instead of the full scale, which captures a hostile submissive interpersonal style associated with depression.

Limitations. It is possible that a relatively modest sample size might not have been sufficient to detect predicted effects. Furthermore, the responses on the questionnaires might not have been representative of the clinical population and could have been affected by social desirability bias.

Conclusions. The results from this study were not in line with the previous research and did not provide further evidence for the relationships between the studied constructs. However, due to the limitations of the study, the findings should be interpreted with caution. Future studies ought to ensure that the samples are of sufficient size and that the participants are either at the pre-treatment stage when completing the questionnaires, or that the stage of therapy is controlled for.

Key words: chronic depression; persistent depression; childhood trauma; pre-operational thinking, interpersonal difficulties

4.2. Introduction

4.2.1. Persistent depression

Persistent depressive disorder (PDD) (American Psychiatric Association, 2013) has been defined in DSM-V as depressed mood which continues to last, for more days than not, for at least 2 years, and is accompanied by two additional symptoms from the suggested list (see Appendix B). This often disabling and challenging mental health condition affects approximately 2–5% of the UK population (National Institute for Clinical Excellence, 2009). It has been established that about 30% of depressed individuals and 47% of the population accessing mental health services are affected by chronic forms of depression (Arnow & Constantino, 2003; Gilmer et al., 2005; Satyanarayana et al., 2009, Torpey & Klein, 2008).

Chronic depression (CD) is often associated with an early age of onset (Berndt et al., 2000), higher incidents of trauma (Klein & Santiago, 2003), and poorer social functioning (Ley et al., 2011; Wittchen et al., 2011). A study by Negele and colleagues (2015) found that 75.6% of chronically depressed patients had a history of childhood trauma. Furthermore, patients who have been diagnosed with persistent depression (PD) have been found to engage in a higher use of health services, suffer from more episodes of illness, spend more time in hospital, report higher rates of self-harm, and have poorer socio-economic status (Arnow & Constantino, 2003; Howland, 1993; Torpey & Klein, 2008). Study by McMahon et al. (2012) demonstrated that an average healthcare cost associated with chronic depression over the period of 3 months was £523 as compared to £460 spent on a patient with recurrent depression. Given the evidence indicating the high level of global burden associated with PDD, the research exploring theories of chronic depression is highly desirable. Advancing our understanding of psychological mechanisms which contribute to and maintain depressive symptoms is likely to lead to more refined and efficacious interventions, which in turn could reduce the risk of relapse. Surprisingly, despite more than 500 randomised trials focusing on the effects of psychotherapy on depression in the adult population, only 16 of the trials included in the meta-analysis by Cuijpers et al. (2010) were studies investigating psychological therapies for PDD.

4.2.2. Cognitive Behavioural Analysis System of Psychotherapy

4.2.2.1. Focus of Cognitive Behavioural Analysis System of Psychotherapy

Cognitive Behavioural Analysis System of Psychotherapy (CBASP*)* has been developed specifically to treat adults affected by PDD (McCullough, 2000; 2001; 2002; 2006). CBASP can be seen as primarily a behavioural therapy in which interpersonal behaviours and their consequences are the main focus. Using a number of therapeutic tools, CBASP therapists help patients to reflect on the interpersonal consequences of their habitual, and often maladaptive, interpersonal behaviours. Once the connection between the problematic interpersonal behaviours and their consequences is established, the individual is encouraged to identify alternative behaviours, which are likely to lead to improved interpersonal 'connectedness'. Such interpersonally focused, goal-directed problem solving is aimed at helping the individual to navigate social situations, and as a consequence, experience a novel set of reinforcements occurring in the person's the environment (Swan & Hull, 2007; Swan et al., 2014).

4.2.2.2. Theoretical underpinnings

The conceptual and clinical framework of CBASP has its roots in the theory of cognitive development (Piaget, 1926), interpersonal theory (Kiesler, 1983), behavioural theory (Skinner, 1953; 1969), and social learning theory (Bandura 1977a, 1977b). The theoretical model CBASP is based on states that the early onset PDD is a consequence of an impairment in cognitive-emotional development and interpersonal functioning, which can be explained by experiences of childhood adversity (McCullough, 2003) (see Figure 1 below).

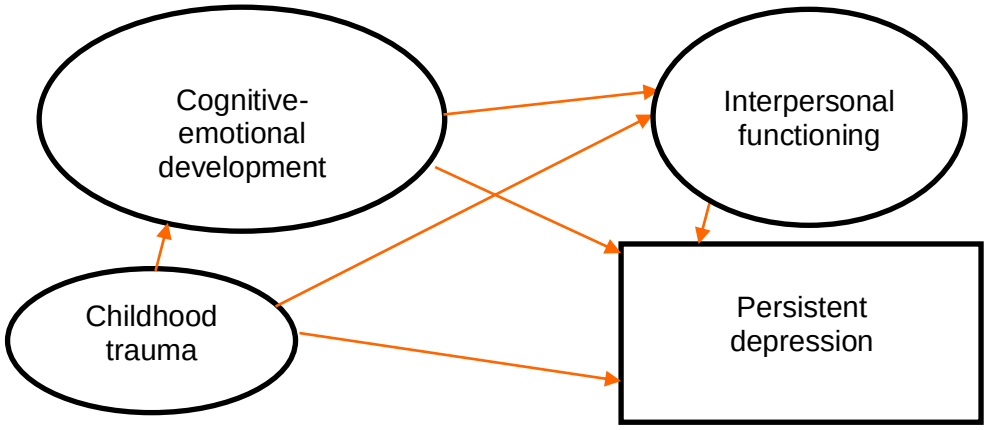

Figure 1. CBASP model

According to McCullough (2003), adverse childhood events such as trauma prevent a young person from developing an ability to think at the operational level, which is characterised by logical reasoning and flexibility of thought (Piaget, 1926) when interacting with others. The inability to engage in the operational way of thinking limits the person's understanding of often nuanced, interpersonal dynamics. According to McCullough, even adult individuals who suffered stressful life events later in life can revert to functioning at the pre-operational levels. Functioning at the pre-operational levels does not allow the individual to notice the connections between their behaviours and the emotional as well as interpersonal aspects of their lives which, in turn, is thought to lead to PDD.

4.2.2.3. Empirical evidence supporting the relationships within the CBASP model

A number of previous studies provided empirical evidence for the relationships between different variables present in the CBASP model.

Childhood trauma and depressive symptoms

Childhood trauma has been linked to the onset, symptom severity and the course of depression (Gibb et al., 2007). In the majority of reported cases, the first episode of PDD is characterised by early onset i.e. it begins before a person turns 21 years old (Barbui et al., 2006; Cassano et al., 1992; Klein et al., 1999), and is often associated with childhood trauma (Lizardi et al., 1995; Wiersma et al., 2009). In fact, epigenetic study carried out by Caspi and Caspi

(2003) has indicated that a genetic vulnerability can be associated with the depressive symptomatology only if the person experienced trauma in earlier life.

Childhood trauma, cognitive-emotional development and depressive symptoms

According to McCullough, a chronically depressed individual has not developed operational ways of thinking in the interpersonal domain as a result of childhood trauma which can affect the person's ability to empathise with others. Operational and formal operational ways of thinking are characterised, among other things, by logic, ability to view things from another individual's perspective, metacognition, and abstract thought (Piaget, 1926). In more recent literature, the ability to reflect upon one's state of mind and feelings is often referred to as mentalisation (Fonagy, 1989) or reflective functioning (Fonagy et al., 1998). Two specific impairments have been associated with reflective functioning; hypomentalising and hypermentalising (Fonagy et al., 2016). Hypomentalising, which has been previously linked to depression (Lemma et al., 2011; Luyten & Fonagy, 2013) is an inability to generate complex models of one's own mind and that of others. Hypermentalising, on the other hand, occurs when a person develops mentalistic representations of one's own or other actions without sufficient evidence.

Importantly, the research findings in this area are largely inconclusive. A study carried out by Vander et al. (2010) revealed that individuals who have been diagnosed with early-onset PDD have demonstrated significantly lower levels of formal reasoning as measured by the Arlin Test of Formal Reasoning (Arlin, 1984) when compared to non-depressed participants. A number of studies have also shown lower levels of reflective functioning in depressed individuals as compared to non-clinical samples (Fischer-Kern et al., 2008; Fischer-Kern et al., 2013). Furthermore, the research has found that early trauma correlated with the impaired development of mentalisation abilities (Allen et al., 2012), and childhood adversity predicted low levels of reflective functioning (Chiesa & Fonagy, 2014). A study by Ensink and colleagues (2016) found that children's capacity to mentalise partially mediated the relationship between child sexual abuse and depressive symptoms. In

contrast, a study by Taubner et al. (2011) found no difference in reflective functioning between chronically depressed patients receiving psychoanalytic treatment and healthy controls. Similarly, a study by Buckley (2017) which explored the relationship between reflective functioning and depression established that individuals with PD were no different in their ability to mentalise when compared to their therapists. The same study found that patient's level of mentalisation had no impact on depressive symptoms. The studies exploring theory of mind abilities (i.e. the ability to attribute mental states in self and others) in depressed samples have also produced mixed results (Mattern et al., 2015; Wilbertz et al., 2010; Zobel et al., 2010).

Childhood trauma, cognitive-emotional development, interpersonal difficulties and depressive symptoms

Previous studies have established that trauma has a negative impact not only on the capacity to mentalise but also on interpersonal functioning. There is an abundance of research indicating that childhood abuse can lead to difficulties with developing secure attachments and healthy relationships in later life (Briere & Elliott, 2003; Liem & Boudewyn, 1999). The aforementioned study by Shipman et al. (2000) demonstrated that sexually abused girls had difficulties with understanding and regulating their emotions, expected less emotional support from others and reported more interpersonal problems than their non-abused peers. Wilson and Scarpa (2015) found that interpersonal difficulties related to hostility, emotional reactivity, inability to collaborate, and isolation, mediated the relationship between childhood sexual abuse and depressive symptoms. Leader and Klein (1996) found an overall impairment in social functioning in PDD. Importantly, a meta-analysis by Renner et al. (2014) established that improvements within the area of social functioning were associated with improvements in depressive symptoms. Learning to navigate challenging interpersonal situations through CBASP techniques predicted patient's improvement of depressive symptoms (Klein et al., 2011; Santiago et al., 2005).

It is worth noting that according to McCullough (2000) patients diagnosed with PDD exhibit a socially avoidant/hostile-submissive interpersonal style which limits their opportunities to experience rewarding

interactions. Such view is in line with a meta-analysis by Bird and colleagues (2018) who also found that individuals with PDD tend to show higher levels of hostile submissive interpersonal style than those with a diagnosis of MDD. Subgroup analyses revealed large effect sizes for hostile-submissiveness among chronically depressed patients (d=0.93).

4.2.3. Rationale and aims

Despite a significant socio-economic burden associated with PDD, this mental health condition is not very well understood. Research findings regarding the efficacy of psychotherapies for PDD are relatively modest (Constantino et al., 2008; Cuijpers et al., 2010; Spijker et al., 2013; Stimpson et al., 2002). Despite a limited evidence base CBASP has been recommended as the first line of treatment for PDD in the Matrix (2015) and in the most recent NICE guidelines (National Institute for Clinical Excellence, 2017) which are still at the second consultation period (more specifically, NICE recommended CBASP or CBT in combination with antidepressant medication). The Matrix guidelines used Keller's et al. (2000) randomised controlled trial (RCT) to support its recommendation and graded the quality of this evidence as being in B category (based on the fact that it was a large RCT providing support for effectiveness of CBASP). The NICE guidelines reviewed a number of RCT's exploring the effectiveness of CBASP and rated the quality of the evidence as ranging from very low to low in the majority of cases. Importantly, as the NICE guidelines pointed out, the quality of evidence was similar across all the studies exploring the effectiveness of psychological interventions on chronic depression not just the research exploring benefits of CBASP.

Given the above recommendations, it is important that professionals who work therapeutically with patients affected by PD are trained in delivering CBASP intervention. The NICE guidelines argue that due to a limited number of therapies which have been shown to be effective for people affected by PD, it is likely that the potential costs associated with training health professionals in CBASP will be balanced by the improved treatment outcome for this population and reduced costs of healthcare provision. Importantly, in order to be able to deliver therapy in a skilled and efficient manner, the therapist needs

to have a solid understanding of the aetiology of the difficulties and, perhaps, even more importantly of the mechanisms that maintain the difficulties. While the extensive research demonstrated a strong link between childhood trauma and mental health difficulties later in life, the specific mechanisms mediating the relationships between trauma and PDD are unclear. For example, the empirical support provided by the previous research for the association between pre-operational functioning and the other three variables in the model, has been inconclusive. An improved understanding of the aetiology of PDD and its maintenance factors is likely to lead to the development of more effective and better tailored treatments. The knowledge of specific mechanisms contributing to PDD could help therapists to plan interventions which specifically address these processes. A better understanding of PDD could also help health services to develop research-informed strategies for early intervention and prevention programmes. Given the strong theoretical foundations for McCullough's model of chronic depression and empirical findings exploring the relationships between the concepts included in the model, it seems like the next step is to establish the evidence for the model as a whole. To the author's knowledge there have been no studies testing the overall CBASP model in one study as of yet. Furthermore, the studies exploring particular concepts addressed by the model rarely focused on patients affected specifically by PDD.

The proposed study will seek to expand on empirical evidence supporting the model proposed by McCullough (2000; 2006). The CBASP theory will be explored using multiple regression analysis which will allow the researcher to establish associations between the concepts included the model.

4.2.4. Research questions

Q1: Is there a relationship between childhood trauma, pre-operational thinking, interpersonal difficulties and depressive symptoms in individuals with PD?

Q2: Is childhood trauma associated with the development of PD?

Q3: Is childhood trauma associated with the difficulties with operational thinking?

Q4: Is childhood trauma associated with the development of interpersonal difficulties?

Q5: What is the interpersonal profile of patients with PD?

4.3. Methodology

4.3.1. Design

A cross-sectional design was used to address the aims of the research. This type of design has a number of advantages, as it is inexpensive to carry out and it can be done in a relatively short period of time as the data is gathered only at one point in time. It can also explore a number of variables at any give time. The researcher presented the study proposal to the group of experts by experience via online forums. The feedback was overwhelmingly positive with regards to the aim and design of the study, and no changes were made as a result of it.

4.3.2. Participants and sample size

Patients were invited to the study if they were above 18 years old; met the DSM-V criteria for PDD; were fluent in English; and were able to provide an informed consent. Patients were excluded if they suffered from psychosis or were unable to provide an informed consent at the time. Clinicians from fourteen different teams which were part of the local NHS Board were also introduced to the study. The teams included Primary Care Mental Health Teams, Psychological Therapies Services, Community Mental Health Teams and Older Adults Teams. Ninety-two clinicians were introduced to the study by the main researcher during pre-arranged meetings.

The primary objective of this study was to gather rich data that would allow the researcher to better understand the theoretical model behind CBASP. Power calculation for a multiple regression analysis with three predictors was carried out by the G*Power programme version 3.9.1.2. (Faul et al., 2009) to determine a sufficient sample size using an alpha of 0.05, a

power of 0.95, and a large effect size (f^2 = 0.35). Based on the aforementioned assumptions, the desired sample size was 33.

4.3.3. Measures

Five questionnaires were used to collect data. It is worth noting that the choice of the measures suitable to use in this study was limited due to the cost associated with well-established measures which have been used in the past studies on chronic depression e.g. the Beck's Depression Inventory (BDI, Beck et al., 1996) or the Childhood Trauma Questionnaire (CTQ, Bernstein et al., 1998).

Child Abuse and Trauma Scale (CATS; Sanders & Becker-Lausen, 1995)

In order to assess early adverse childhood experience the CATS was used. The CATS is a 38-item self-report measure of childhood abuse that focuses on several components of traumatic experiences. Factor analysis on the CATS produced three distinct subscales such as sexual abuse; punishment; and negative home environment/neglect. The CATS was shown to have good internal consistency (α = .63–.90) (Kent & Waller, 1998), strong test-retest reliability (r= 0.89), and a reasonable convergent validity (r= 0.29) (Sanders & Becker-Lausen, 1995).

Luebeck Questionnaire for Recording Preoperational Thinking (LQPT, Kuhnen et al., 2011)

The LQPT is a self-report questionnaire assessing pre-operational thinking in chronically depressed adults. It consists of 22 scenarios which illustrate a number of potentially difficult interpersonal situations. Different aspects of preoperational thinking (snapshot perspective, prelogical thinking, egocentrism, lack of perceived functionality, and lack of empathy) are assessed by the questionnaire. A low total score on the measure is associated with a high level of preoperational thinking. The study by Kuhnen and colleagues using a sample consisting of 30 episodically depressed, 30 chronically depressed, and 30 healthy volunteers demonstrated that the German version of LQPT has good construct validity and internal consistency (Cronbach's alpha = 0.90). The study has found that the scores on the LQPT

were able to distinguish between chronically and episodically depressed patients. The study by Sargin and colleagues (2018) has demonstrated good validity and reliability of the Turkish version of the measure.

Reflective Functioning Questionnaire (RFQ-8, Fonagy et al., 2016)

In order to assess the ability to think at operational levels, another questionnaire was used alongside the LQPT. The RFQ-8 is a self-report measure which assesses one's capacity to perceive and interpret the intentional mental states of others. Although there are no articles known to the researcher exploring reliability and validity of the RFQ-8, the eight items included in the RFQ-8 were all part of the original RFQ with research findings supporting its reliability and validity (Badoud et al., 2015; Fonagy et al., 2016). The RFQ has been found to have very good reliability and internal consistency (Cronbach's alpha 0.82) (Fonagy et al., 2016). Validation studies of the RFQ revealed a two-dimension model; the Certainty of Mental States subscale which measures hypermentalising (RFQ-c) and the Uncertainty of Mental States subscale which measures hypomentalising (RFQ-u). This study will focus specifically on the subscale measuring hypomentalising which was found to be associated with depression.

Inventory of Interpersonal Problems (IIP-32; Horowitz et al., 2000)

In order to assess interpersonal difficulties, the IIP-32 was used. The IIP-32 measures an overall interpersonal distress and each of its 8 sub-scales represents a separate problematic interpersonal behaviour such as difficulties with being assertive, sociable, supportive, and/or involved, as well as, being too caring, dependent, aggressive, and open. The IIP-32 is based on a circumplex structure of interpersonal problems categorizing interpersonal problems into eight subscales, which can be arranged in two dimensions and define a circumplex. These two dimensions are affiliation (hostile vs. friendly) and dominance (domineering vs. yielding). Cronbach's alpha (0.82) and half-split coefficients (0.82) showed that reliability of this scale is suitable (Fath et al., 2013). Internal consistency estimates and inter-scale correlations were generally high and confirmed the proposed circumplex structure (Bailey et al.,

2018).

Patient Health Questionnaire (PHQ-9, Spitzer et al., 1999)

In order to assess current depressive symptoms, the PHQ was used. The PHQ-9 is a self-report measure that is used to assess the severity of depression. It is mostly based on the DSM-IV depression diagnostics criteria. A high score on the PHQ-9 indicates a high severity of depression. PHQ-9 scores less than or equal to 10 had a sensitivity of 88% and a specificity of 88% for major depression. The PHQ-9 was shown (Kroenke et al., 2001) to have both construct and criterion validity as well as excellent internal reliability (Cronbach's α of 0.89). The study by Martin et al. (2006) found the PHQ-9 to be reliable and valid in identifying major depression as well as recognising milder presentations in the general population.

The authors of the questionnaires were asked for the permission to use them.

Demographics & chronicity of depression

Participants were also asked to answer a number of closed-ended questions aiming to gather some basic demographic information regarding their age, gender, years of education, relationship status, ethnicity, and the length and onset of their depression.

4.3.4. Ethics

This study was granted ethical approval by the West of Scotland Research Ethics Committee in 2019 (REC ref no: 18/WS/0231; see Appendix I). The associated NHS Research and Development Office also provided approval for this study (R&D ref no 2018/0315; see Appendix J). The participant data was kept anonymous at each stage of the research process. An online tool was used to generate random numbers, which were then assigned to participant's data. A paper sheet linking ID number to participant name was kept in a locked filing cabinet and only accessible by the lead researcher. Data was saved in a password protected folder on an NHS and University of Edinburgh computer.

4.3.5. Procedure

Following the ethics approval, the researcher liaised with Clinical Psychologists and Psychiatrists from each of the 14 different Adult Mental Health Services who expressed an interest in supporting the study following an e-mail invitation from the researcher. The researcher then visited each of the team and, if possible, attended one of the team meetings and introduced the study to all the clinicians attending the meeting. The study was explained to the teams using charts and FAQ (frequently asked questions) sheets. After explaining the study and answering any related questions, clinicians who expressed an interest in the study were asked to consider individuals on their current caseload who met the inclusion and exclusion criteria. The clinicians were then invited to briefly describe the study to the suitable patients from their caseload, the next time they saw someone for an assessment or as part of treatment. If the identified patient was interested in finding more about the study following a brief description, the clinician was asked to then pass on to the patient a pre-paid envelope containing a patient information sheet, consent forms, and a questionnaire pack. The clinician was also asked to instruct the patient to carefully read the information sheet at home, and if the person still wished to take part in the study at that point, to complete the questionnaires and either send them back or hand them back to the clinician in the provided envelope.

In order to introduce the study to as many clinicians and patients as possible, as well as comply with the data protection policies, the researcher's contact with the patients was kept to a minimum. The researcher spoke directly to the patient about the study only if the patient had already been seeing the researcher for therapy, or if the patient was looking for more information and, either contacted the researcher or consented to be contacted by the researcher. The questionnaires returned by the patients were sent to the researcher's clinical supervisor's NHS address either by the patient or by the clinician who introduced the patient to the study. The researcher's clinical supervisor passed the questionnaires onto the researcher as they arrived. The researcher opened the questionnaire packs, and following the anonymisation, separated the consent forms from the questionnaires. The researcher typed

the data from the questionnaires onto the NHS and University of Edinburgh computer using available software.

For the copies of the patient's information sheet, patient's consent sheets, and the information sheet for the clinicians, please see Appendices I, J, and K respectively.

4.3.6. Data analysis

The study aimed to test a developmental model of PD proposed by McCullough (2000; 2006). At the initial stages of the project, there was a plan to use the Structural Equation Modelling (SEM) method which is a combination of multiple regression and factor analysis and can be used to analyse structural relationships (Hoyle, 1995). Testing hypotheses using SEM can be helpful in understanding directional and non-directional relationships connecting a number of observed and latent variables (MacCallum & Austin, 2000). Importantly, Ding and colleagues (1995) identified numerous studies proposing that 100 to 150 subjects is the minimum satisfactory sample size when conducting SEM. Unfortunately, identification of clinicians working with PD who would be willing to support the study proved to be challenging, and as a result the sample size recruited was insufficient for SEM analysis. Given the relatively modest sample recruited for the study, it was decided that multiple regression will be the most appropriate method to use in order to explore the relationships between the variables that are included in the McCullough's model.

A series of multiple regression analyses were conducted using the SPSS, version 24.0.0.2. (2013). It was ensured that the data met the assumptions of normality, linearity, homoscedasticity, and absence of multicollinearity by producing and analysing the model fit, probability plot and collinearity diagnostics in the SPSS. Enter method was used to enter the data into the system in order to assess the contribution of each independent variable to the model and to establish whether this addition is significantly different from the predictions revealed by the other variables entered into the model. This type of statistical analysis allows the researcher to explain the relationship between one continuous dependent variable (in this study: PD) and two or more independent variables, also called predictors (in this study:

trauma, cognitive-emotional development and interpersonal functioning). Average imputation was employed to manage missing data due to the 25 items not being completed across the sample (0.08% of data). The average value of the responses from the other participants were used to fill in the missing values. Importantly, due to the exploratory nature of this study, a number of analyses has been conducted as long as they were seen as relevant and novel. The decision was made to include these analyses in the write-up regardless of the established statistical significance of the outcomes in order to use this opportunity to explore any emerging patterns.

4.4. Results

4.4.1. Sample characteristics

Thirty-two patients completed and returned the questionnaire pack. Demographic and clinical characteristics of the sample are presented in Tables 1 and 2 below. While the most frequent age bracket for the participants was 40 to 49, the age range of the sample was between 21 and over 60 years old. Females comprised just above half of the sample. The majority of the sample was educated to a higher level. Just above the half of the participants were in employment, and none of the unemployed participants were actively looking for a job. Nearly half of the participants never married, with almost one third being divorced. All participants bar one reported to be of white ethnicity.

Fifty-nine percent of the participants experienced early onset of depression (before the age of 21) while the majority of the participants reported the duration of their current episode to be longer 5 years. For more detailed information see Table 1 and 2 below.

Table 1
Demographic characteristics of the study sample (N=32)

		N (%)
Age		
	21-29	7 (22)
	30-39	5 (16)
	40-49	8 (25)
	50-59	6 (19)
	60+	6 (19)
Gender		
	Male	14 (44)
	Female	18 (56)
Ethnicity		
	White	31 (97)
	African	1 (3)
Education		
	None	1 (3)
	High School	5 (15)
	College Degree	7 (22)
	Bachelor's Degree	12 (38)
	Postgraduate Degree	7 (22)
Employment		
	Part-Time	7 (22)
	Full-Time	10 (31)
	Retired	5 (16)
	Not Employed	5 (16)
	Unable to Work	5 (16)
Marital Status		
	Married	7 (22)
	Divorced	10 (31)
	Widowed	1 (3)
	Never Married	14 (44)

N (number of participants)

Table 2
Clinical characteristics of the study sample (N=32)

		N (%)
Age of Onset		
	≤ 11	7 (22)
	12-17	11 (34)
	18-20	1 (3)
	21-29	5 (16)
	30-39	3 (9)
	40-49	5 (16)
Episode Duration		
	2 years	0 (0)
	>2 years	10 (31)
	>5 years	22 (69)

N (number of participants)

4.4.2. Interpersonal profile

The Inventory of Interpersonal Problems provided a measure of interpersonal profile of the sample. Figure 2 illustrates the IIP-32 scores for the whole sample which were graphed onto the interpersonal circumplex.

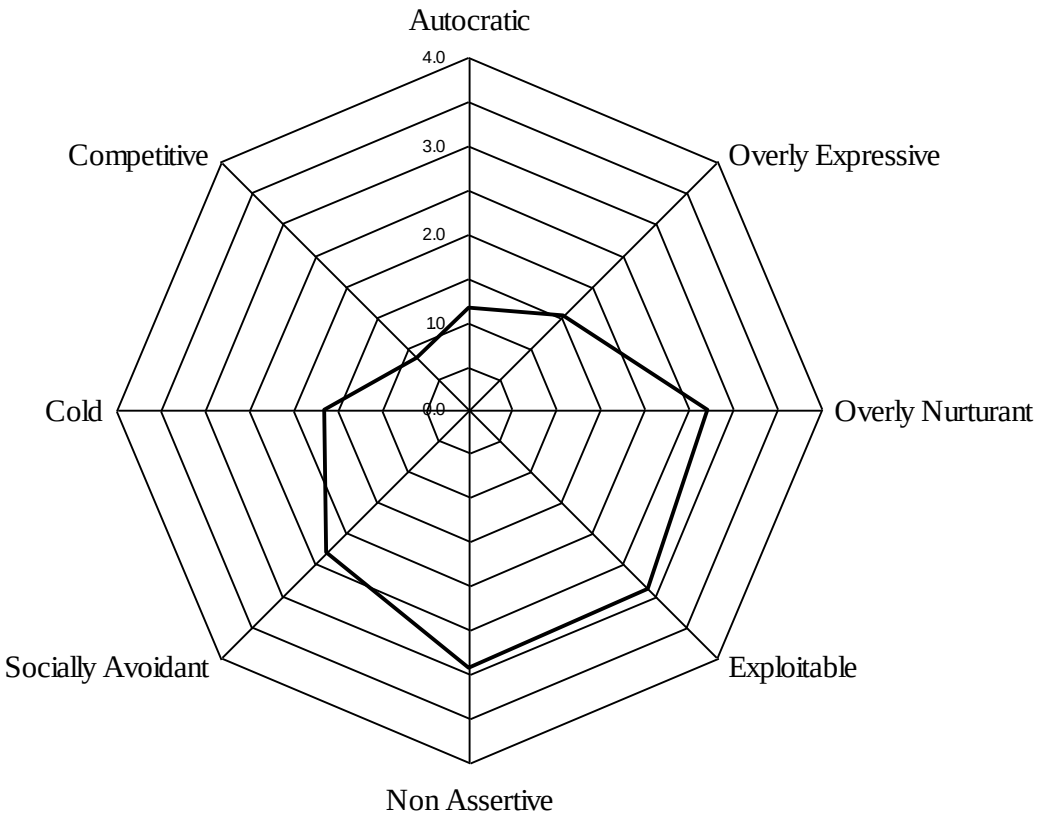

Figure 3. Interpersonal profile of the participants

On average, participants in the current study exhibited a tendency to be socially avoidant as opposed to overly expressive (hostile submissive vs friendly dominant*), non assertive as opposed to autocratic (submissive as opposed to dominant*), exploitable as opposed to competitive (friendly submissive as opposed to hostile dominant*), and overly nurturant as opposed to cold (friendly vs hostile*).
*terminology used by McCullough/CBASP

Means and standard deviation (SD) scores of all eight IIP-32 subscales for the PDD sample from the current study and for a non-clinical sample from the Locke et al.'s (2017) study are presented in Table 3 below. The normative

sample in the Locke et al.'s study consisted of 361 respondents and included English-speaking citizens of the United States and Canada who were recruited from the general population using Amazon's Mechanical Turk (MTurk) website (Buhrmester et al., 2015). Online statistical software MedCalc (2020) was used to compare means and SD's of the PDD sample from this study and the normative sample from the Locke et al.'s study on all eight IIP subscales. It was found that the PDD sample experienced more interpersonal difficulties across all of the subscales except one (competitive/dominant hostile) indicating an overall difficulty across the interpersonal circumplex. The differences between the groups were statistically significant (see Table 3).

Table 3

Interpersonal difficulties in depressed and normative samples

	PDD Sample		Normative Sample			
Interpersonal Profile	*Mean*	*SD*	*Mean*	*SD*	*t*	*df*
Autocratic/Dominant	0.98	1.02	0.63	0.66	-2.729**	391
Competitive/Dominant Hostile	0.81	1.07	0.80	0.80	-0.066	391
Cold/Hostile	1.63	1.31	0.99	0.84	-3.915**	391
Socially Avoidant/Hostile Submissive	2.30	1.26	1.66	1.07	-3.194**	391
Non Assertive/Submissive	2.93	1.20	1.75	0.97	-6.461**	391
Exploitable/Friendly Submissive	2.88	1.26	1.67	0.88	-7.163**	391
Overly Nurturing/Friendly	2.70	1.32	1.76	0.97	-5.085**	391
Overly Expressive/ Friendly dominant	1.56	1.34	0.77	0.74	-5.327**	391

Notes: **.difference was significant at the 0.01 level; Abbreviations: SD (standard deviation)

4.4.3. Primary analysis

4.4.3.1. Descriptive statistics

Table 4 illustrates means and standard deviations of each of the outcome measures used in the primary analysis.

Table 4
Descriptive statistics for key variables (N=32)

Variable	Mean	SD
Depression	16.03	6.07
Childhood Trauma	53.55	27.64
Pre-operational Thinking	14.05	4.90
Hypomentalising	6.63	3.63
Interpersonal Difficulties	63.21	16.14
Hostile-Submissive Interpersonal Style	9.22	3.60

Abbreviations: N (number of participants), SD (Standard Deviation)

4.4.3.2. Correlation analysis

Correlation analysis was run for all of the outcome measures which were completed by the patients (see Table 5). The RFQ questionnaire consists of two subscales which needed to be calculated separately in order to provide meaningful data relating to the hypermentalising and hypomentalising aspects of reflective functioning. In the light of evidence (Bird et al., 2018) suggesting that patients with PDD are more likely to be hostile submissive (or socially avoidant) in their interpersonal style, this particular subscale of the IIP was included in the analysis alongside the total IIP score.

Firstly, two subscales of the RFQ scale were found to be negatively correlated suggesting a negative association between hypomentalising (RQF-u) and hypermentalising (RFQ-c), which is not surprising given that these two impairments can be seen as opposite to each other. Unsurprisingly, a positive moderate association was found between the full IIP scale and the hostile-submissive subscale. Importantly, none of the other associations were found to be statistically significant. It is worth noting, however, that a moderate positive association between the outcomes on the RFQ-u and LQPT nearly reached statistical significance ($p < .06$) which might be indicative of these two subscales measuring similar impairments. A positive association between the outcomes on the LQPT and IIP also nearly reached statistical significance (p

< .08) indicating that that the association between pre-operational thinking and interpersonal difficulties might have been demonstrated with the larger sample size.

Table 5

Correlations of key variables (N = 32)

Variable	1	2	3	4	5	6	7
1. Childhood Trauma	-						
2. Hypomentalising	-.233	-					
3. Hypermentalising	-.064	-.470*	-				
4. Pre-operational Thinking	-.040	-.336	0.348	-			
5. Interpersonal Difficulties	.073	-.020	-0.74	-0.310	-		
6. Hostile-Submissive Interpersonal Style	.235	-.050	.230	-0.183	.464**	-	
7. Depression	.204	.110	-.074	-.258	.254	.190	-

Notes: All computed as Pearson's rs; *correlation is significant at .05 level (2-tailed); **correlation is significant at .01 level (2-tailed); Abbreviations: N (number of participants)

4.4.3.3. Model 1. Multiple regression using the outcomes on CAT, LQPT, IIP as predictors and the outcome on PHQ as a dependent variable

Multiple regression analysis was carried out to investigate whether childhood adversity, thinking at pre-operational levels, and interpersonal difficulties could significantly predict levels of depression in the PDD sample. The results of the first regression analysis (see Table 6) indicated that the model seemed to have explained only 13% of the variance and it was not a significant predictor of depressive symptoms (F (3,28) =1.44, p < .26). Childhood adversity, thinking at pre-operational levels, and/or interpersonal difficulties did not contribute significantly to the model.

Table 6
Summary of Multiple Regression Analysis (N=32)

		B	***SE***	***β***	***t***	***R^2***	***Adjusted R^2***	***F***
Model 1								
	Overall Model					.04	.01	1.31
	Childhood Trauma	.05	.04	.20	1.14			
Model 2								
	Overall Model					.10	.04	1.68
	Childhood Trauma	.04	.04	.19	1.11			
	Pre-Operational Thinking	-.31	.22	-.25	-1.42			
Model 3								
	Overall Model					.13	.04	1.44
	Childhood Trauma	.04	.04	.18	1.04			
	Pre-Operational Thinking	-.24	.23	-.19	-1.05			
	Interpersonal Difficulties	.07	.07	.18	.97			

Notes: Pre-operational thinking as measured by LPQT (*Kuhnen et al., 2011)*

; * p < .05 ** p < .01; Abbreviations: N (number of participants)

4.4.3.4. Model 2. Multiple regression using the outcomes on CAT, RFQ-u, IIP as predictors and the outcome on PHQ as a dependent variable

Another multiple regression analysis was performed using RFQ-u rather than LQPT as a measure of pre-operational thinking (see Table 7). The results of the regression indicated that the model using RFQ-u instead of LQPT also seemed to have explained only 13% of the variance and it was not a significant predictor of depressive symptoms (F(3,28) =1.35, p < .29).

Childhood adversity, thinking at pre-operational levels, and/or interpersonal difficulties, did not contribute significantly to the model.

Table 7
Summary of Multiple Regression Analysis (N=32)

		B	*SE*	*β*	*t*	R^2	Adjusted R^2	*F*
Model 1								
	Overall Model					.04	.01	1.31
	Childhood Trauma	.45	.04	.20	1.14			
Model 2								
	Overall Model					.07	.00	1.06
	Childhood Trauma	.05	.04	.24	1.32			
	Pre-Operational Thinking	.28	.31	.17	.97			
Model 3								
	Overall Model					.13	.03	1.35
	Childhood Trauma	.05	.04	.23	1.24			
	Pre-Operational Thinking	.28	.30	.17	.92			
	Interpersonal Difficulties	.09	.07	.24	1.37			

Notes: Pre-operational thinking as measured by RFQ-u (*Fonagy et al., 2016)*; * p < .05 ** p < .01; N (number of participants)

4.4.4. Secondary analysis

4.4.4.1. Model 3. Multiple regression using the outcomes on CAT, LQPT and hostile submissive/socially avoidant subscale of the IIP (*IIPHosSub) as predictors and the outcome on PHQ as a dependent variable*

Given the literature indicating that individuals with PDD have tendency to exhibit hostile submissive interpersonal style, the secondary analysis included the hostile submissive/socially avoidant subscale of the IIP in the model instead of the total IIP score. LQPT was used as a measure of preoperational thinking, as despite not reaching statistical significance in the correlation analysis, the results have suggested that there might have been a stronger association between the LQPT and PHQ than between the RFQ-u and PHQ. The regression analysis indicated that the model using IIPHosSub instead of the full IIP scale seemed to have explained only 11% of the variance (Table 8), and it was not a significant predictor of depressive symptoms ($F(3,28) = 1.11$, $p < .36$). Childhood adversity, thinking at pre-operational levels, and/or interpersonal difficulties, did not contribute significantly to the model. Using the IIP subscale did not result in a greater variance within the model being accounted for.

Table 8
Summary of Multiple Regression Analysis (N=32)

		B	*SE*	*β*	*t*	R^2	Adjusted R^2	*F*
Model 1								
	Overall Model					.04	.01	1.31
	Childhood Trauma	.05	.04	.20	1.14			
Model 2								
	Overall Model					.10	.04	1.67
	Childhood Trauma	.04	.04	.19	1.11			
	Pre-Operational Thinking	-.31	.22	-.25	-1.42			
Model 3								
	Overall Model					.11	.01	1.11
	Childhood Trauma	.04	.04	.19	1.02			
	Pre-Operational Thinking	-.30	.22	-.25	-1.37			
	Interpersonal Difficulties	.19	.68	.05	.28			

Notes: IIP Hostile submissive subscale was entered into the model as one of the predictors instead of a full IIP scale (*Horowitz et al., 2000)*; * p < .05 ** p < .01; N (number of participants)

4.4.4.2. Model 4. Multiple regression using the outcomes on CAT and LQPT as predictors and the outcome on IIPHosSub as a dependent variable

Another analysis was performed to investigate whether childhood adversity and thinking at pre-operational levels as measured by LQPT could predict the levels of hostile-submissive interpersonal style in the PDD sample. The results of the regression indicated that the model using the outcomes on CAT and LQPT predicted only 4% of the variance and it was not a significant predictor of hostile-submissive interpersonal style ($F(3,28) = 0.56$, $p < 0.59$). Childhood adversity and/or thinking at pre-operational levels did not predict the hostile-submissive interpersonal style.

Table 9
Summary of Multiple Regression Analysis (N=32)

		B	*SE*	*β*	*t*	R^2	Adjusted R^2	*F*
Model 1								
	Overall Model					.03	.00	.95
	Childhood Trauma	.01	.01	.18	3.12			
Model 2								
	Overall Model					.04	-.03	.56
	Childhood Trauma	.01	.01	.17	.94			
	Pre-Operational Thinking	-.26	.06	-.08	-.44			

Notes: Hostile submissive subscale was entered into the model as a dependent variable instead of a full IIP scale (*Horowitz et al., 2000)*; * p < .05 ** p < .01; Abbreviations: N (number of participants)

4.5. Discussion

4.5.1. Main findings

The aim of this paper was to investigate whether the model of PDD as proposed by McCullough is supported by empirical evidence. According to McCullough's theory, early experiences of childhood adversity can lead to depression characterised by chronic presentation. Furthermore, McCullough hypothesised that the link between childhood adversity and trauma can be explained by an impairment in the cognitive-emotional development and interpersonal functioning which is believed to be a consequence of traumatic experiences. The current study was developed to test these hypotheses using multiple regression analyses.

The findings from this study are somewhat surprising and not in line with previous research. Firstly, no association was established between childhood adversity and severity of depression. Moreover, childhood adversity, pre-operational thinking and interpersonal difficulties did not predict the severity of depressive symptoms, regardless of which measure of pre-operational thinking was used. There was also no evidence to suggest that trauma leads to an impaired interpersonal functioning, even after entering data from the subscale of the IIP capturing hostile submissive interpersonal profile which has been found in the past research to be specifically associated with PDD. Importantly, the interpersonal circumplex for the sample from this study revealed that patients diagnosed with PDD have a tendency to be hostile submissive/socially avoidant, non assertive, exploitable and overly nurturant. When compared with the normative samples, patients from the current study were characterised by greater difficulties across the interpersonal circumplex except for one subscale.

4.5.2. Theoretical implications

The findings from this study suggest the lack of associations between the constructs in the model developed by McCullough. However, given the strength of evidence supporting the links between different concepts included in McCullough's theory of chronic depression, it is quite likely that the lack of significant findings can be attributed to the flaws in the research design rather than the absence of meaningful relationships.

In particular, the impact of childhood trauma on mental health difficulties in adulthood has been well supported by research. Childhood trauma has been specifically shown to be a risk factor for depression in later life both in cross-sectional and longitudinal studies (Kessler, 1997; Molnar et al., 2001; Tanskanen et al., 2004; Widom et al., 2007). Twenty-six studies included in the meta-analysis by Mandelli et al. (2015) which investigated the relationship between childhood trauma and depression reported small to large effect sizes. One of the major differences between the studies included in Mandelli's review and this study is the number of participants (ranging from 66 to 9346 per study). Therefore, it is quite likely that the relationship between trauma and depression has not been found in the current study due to the insufficient sample size to detect small or moderate effects. If the effect or the strength of association exists but it is subtle, the underpowered study will not be able to detect it. Importantly, there is balance to be struck there. While large values of power are desirable, the studies with excessive sample size are more likely to be prone to Type II error and finding effects when, in fact, none exist. An overpowered study can also be unethical given the effort and potential distress experienced by the participants and the associated waste of valuable resources (Suresh & Chandrashekara, 2015). However, if the relationships between the explored variables are indeed weaker than assumed in the power calculation in this study, future research should focus on recruiting a larger number of patients in order to increase the chance of identifying them. It is possible that the design of the study itself can be amended to allow for a greater chance of successful recruitment. This study involved promoting the research in multiple teams and to a large group of clinicians. It might be helpful in the future to establish relationships with a smaller group of professionals who have interest in research.

Furthermore, the present study found no relationship between the outcomes on the measures of preoperational thinking and depressive symptoms which is in line with a number of studies which also found no association between pre-operational thinking and PDD (Buckley, 2017; Taubner et al., 2011; Wilbertz et al., 2010). However, due to the mixed findings reported by the studies investigating the role of pre-operational thinking/reflective functioning in PD, it is difficult to draw strong conclusions

based on the results from the present study. Interestingly, several studies have found the evidence to support the mediating role of emotional regulation abilities in the relationship between trauma and depression (Crow et al., 2014; Huh et al., 2017). Difficulties with self-regulation of affect after experiencing adverse life events might predispose a person to develop depressive symptoms. Indeed, the past research has found that depressed patients show a tendency to adopt maladaptive strategies when regulating their emotions and have difficulties with effective use of adaptive strategies (Joormann & Stanton, 2016). There is also evidence indicating that maladaptive emotion regulation strategies such as suppression of emotional expression have been associated with worse interpersonal functioning as compared to alternative strategies relying on cognitive reappraisal (Gross & John, 2003). An ability to cope with stressful situations might be an alternative to a mediating mechanism of pre-operational thinking suggested by McCullough.

Despite the apparent lack of association between the interpersonal difficulties and the other variables in the model, the participants' profile on the interpersonal circumplex showed a tendency to adopt a hostile submissive as opposed to a friendly dominant interpersonal style, which was in line with the previous research (Bird et al., 2018). Overall, the interpersonal circumplex revealed submissive rather than dominant tendencies for the PDD sample and compared to the normative samples obtained from Locke's study, the participants showed an overall difficulty in the interpersonal domain. Given these emerging patterns, it is likely that the relationship between PDD and interpersonal difficulties was undetected in this study due to the small sample size and other methodological limitations discussed below.

Importantly, the findings relating to the patterns of interpersonal functioning among the individuals affected by PDD are clinically important as they not only point to the specific difficulties with interpersonal functioning that can be targeted in therapy but also help to predict the therapist's interpersonal response towards the patient. A patient behaving in a hostile manner is likely to evoke feelings of hostility in his/her therapist, and similarly, a patient who is being submissive, is likely to invite dominance from his/her therapist (Horowitz et al., 1997; Kiesler, 1983). McCullough (2000) recommends that the therapist understands his/her patient’s interpersonal style early in the treatment to be

able to adopt a friendly interpersonal style despite being pulled towards hostility and dominance. It would be useful to investigate interpersonal styles of different clinical populations as it is highly likely that an awareness of patients' interpersonal styles can be clinically beneficial with different presentations.

While the interpersonal profile of the sample revealed the difficulties in the interpersonal domain, no association was found between interpersonal difficulties and trauma. It is possible that interpersonal difficulties demonstrated in this study can be explained by other factors than trauma. For example, chronically depressed individuals who do not report childhood trauma might struggle in the interpersonal domain due to the reduced motivation to socialise and the lack of confidence associated with their depression. Importantly, in the majority of studies linking depressive symptoms to interpersonal difficulties, causal connections are not clear due to the cross-sectional designs (Leader & Klein, 1996).

Finally, it is possible that McCullough's model of chronic depression is not accurate. If the evidence base for the model lacks strength, this has implications on the therapeutic intervention which is based on that model. Such inconsistent results affect the degree of certainty with which we can make predictions about causes of depression and the maintaining factors hypothesised by the model. If McCullough's theoretical model is incorrect, the evidence indicating the effectiveness of CBASP intervention can be somewhat puzzling. Again, it is extremely important that researchers focus on the actual mechanisms and components of the therapy that lead to clinical changes such as specific CBASP techniques or non-specific factors such as therapeutic relationship. It is necessary to continue building on the past studies in order to increase our confidence in empirical support for the model while exploring other possible explanations.

It is also worth pointing out that while McCullough's model primarily focuses on the early onset PDD, in order to maximise the number of participants taking part, the late onset depression was not an exclusion criterion. In fact, 41% of the sample reported experiencing the first episode later in life. It could be useful to focus specifically on the individuals reporting early onset of PDD in the future studies.

4.5.3. Limitations and avenues for further research

A number of further limitations have been identified that might have contributed to the present findings. Firstly, the outcome measures used, especially the PHQ-9, might not have been the most suitable to capture different levels of severity of PDD, since it was designed as a short screening for MDD. In fact, it has been established in the past (Wittkampf, 2009) that the correlation between the PHQ-9 and HAM-D, the clinician administered measure of severity of depression, is relatively low ($r=0.52$, $p<0.01$). The authors of that study have concluded that while the PHQ-9 might be a good screening tool, it should be accompanied by other measures when assessing the severity of depression. Interestingly, the majority of the previous studies which found the relationship between depressive symptoms and interpersonal functioning or trauma used the BDI (Beck et al., 1996), the HAM-D (Hamilton, 1960), or both. Unfortunately, due to the nature of the project and restricted budget it was not viable to use measures such as the BDI. The BDI-II is a 21-item self-report inventory measuring the severity of depression in adolescents and adults and was revised in 1996 to be more consistent with DSM-IV criteria for depression. A higher number of items on the BDI as compared to the PHQ and good psychometric properties of the questionnaire, would likely allow for a greater depth and precision of the assessment which would, in turn, lead to the increased validity of the results. Similarly, it would have been helpful to use HAM-D which is a clinician administered questionnaire for depression to gain another perspective and perhaps produce more insightful findings.

Moreover, both measures of pre-operational thinking used in the present study (the RFQ-8 and LPQT) are relatively new and not well-established. To the author's knowledge there have been no articles investigating reliability and validity of these two measures with English speaking samples. The items included in the RFQ-8 have only been validated as part of the research validating the original, longer version of the questionnaire, and the LQPT has been validated with German and Turkish speaking samples only. The future studies should focus on validating these questionnaires with English speaking sample. It might have also been useful to use the CTQ measure (Bernstein et al., 1998) instead of the CATS which

has been widely used in the past when exploring trauma and mental health difficulties (Spinhoven et al., 2014). The CTQ has good psychometric properties and has been validated with a number of different populations. In comparison to the CATS measure which has three subscales, the CTQ has five subscales (emotional abuse, physical abuse, sexual abuse, emotional neglect and physical neglect), and as a result, captures broader dimension of childhood maltreatment.

Another major limitation which might have affected the results is the fact that in order to maximise the likelihood of successful recruitment, participants were included to the study regardless of the stage of therapy they were at. In fact, as a way of ensuring patient's suitability for the study and to minimise potential distress associated with filling out the questionnaires, the clinicians may have been more likely to recruit potential participants in the later stages of therapy. A patient who was referred with severe symptoms of depression, might have scored much lower on the PHQ in the middle phase of the therapy as opposed to the initial phase. Similarly, the difficulties in the interpersonal functioning might have reduced by the time a patient was asked to take part in the research. Importantly, the symptom change can occur within first several sessions in the CBASP therapy (Schramm et al., 2015). As a result, the link between the independent variable i.e. the experiences of trauma and the dependent variables could have been weakened for these patients as despite their experience of childhood adversity, their mental health symptoms might have improved by the time they were asked to fill out the questionnaires. It is even possible that some patients have returned the questionnaires after the therapy ended, or when their motivation levels have improved as a result of the reduction in their symptoms. It would have been useful to confirm the diagnosis of PDD with a patient just prior to filling out the questionnaires by the patient.

Furthermore, due to the fact that the clinician who would have introduced the patient to the study was also acting as their therapist, the outcomes reported might have been somewhat inaccurate due to the social desirability bias. Research findings have shown that reporting symptoms of depression by a person affected by this condition is indeed affected by this phenomenon (Fastame & Penna, 2012). Ideally, this study should have been

introduced by an independent researcher to the patients who were pre-treatment.

Finally, the cross-sectional nature of the study and its correlational design do not allow the researcher to make conclusions about causal relationships between the constructs. It would be useful if the future studies employed longitudinal designs which could offer additional insights into the nature of associations between the investigated constructs. Future longitudinal studies could also explore a potential bidirectional relationship between interpersonal difficulties and depression.

4.5.4. Conclusions & implications for future practice

The present study did not provide support for the hypothesised relationships between the constructs in McCullough's model of chronic depression. However, taking previous research findings into account, it is likely that these relationships do, in fact, exist but are perhaps weaker and more nuanced than suggested by McCullough. In order to increase validity and reliability of future findings, researchers should address a number of design flaws present in this study when developing new studies. If the relationships explored in this research are indeed weaker than predicted, it will be useful to increase the sample size to make sure that the future studies have enough power. A larger sample size would also allow the researchers to make meaningful comparisons between the individuals reporting early onset depression with those who have experienced depression later in life. Furthermore, it would be helpful to use measures such as the BDI which might be more valid when assessing the severity of depressive symptoms as compared to their free of charge counterparts such as the PHQ-9. It might also be crucial to ensure that the patients taking part in the future studies have not yet started therapy and are meeting the criteria for PD at the time of completing the questionnaires. Finally, the longitudinal designs, while more difficult and expensive to implement, can offer invaluable insight into causal relationships between studied concepts.

Given the ever-increasing prevalence, chronicity, negative impact on a person's life, and the global burden associated with PDD, it is essential to continue research into this area if we wish to gain a better understanding of

this debilitating condition and recommended treatments. Importantly, the above study draws attention to the model that was developed to treat a condition that is both complex and often treatment resistant. Given the current clinical guidelines and a limited number of treatments which were shown to be effective with the PD population, studies into CBASP will hopefully encourage clinicians to seek training in this area, including developing skills in CBASP delivery. Furthermore, a better understanding of the model of PD is likely to allow healthcare professionals to further tailor the therapeutic interventions they offer to meet the patient's needs, and might aid the development of effective preventative interventions that might decrease the chance of PDD developing in the first place. The lack of statistically significant findings demonstrated in this study, at the very least, encourages us to revisit some of the mechanisms that have been linked to the development of depression in the past. While some of these associations have been supported by past literature, some constructs such as preoperational thinking need further consideration.

4.6. References

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5. Appendices

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Figures

Although authors are encouraged to send the highest-quality figures possible, for peer-review purposes, a wide variety of formats, sizes, and resolutions are accepted. Click here for the basic figure requirements for figures submitted with manuscripts for initial peer review, as well as the more detailed post-acceptance figure requirements.

Figures submitted in color may be reproduced in color online free of charge. Please note, however, that it is preferable that line figures (e.g. graphs and charts) are supplied in black and white so that they are legible if printed by a reader in black and white. The cost of printing color illustrations in the journal will be charged to the author. The cost is £150 for the first figure and £50 for each figure thereafter. If color illustrations are supplied electronically in either TIFF or EPS format, they may be used in the PDF of the article at no cost to the author, even if this illustration was printed in black and white in the journal. The PDF will appear on the Wiley Online Library site.

Additional Files

Appendices

Appendices will be published after the references. For submission they should be supplied as separate files but referred to in the text.

General Style Points

The following points provide general advice on formatting and style.

1. Abbreviations: In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially, use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.
2. Units of measurement: Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Mesures (BIPM) website for more information about SI units.
3. Numbers: numbers under 10 are spelled out, except for: measurements with a unit (8mmol/l); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).

4. Trade Names: Chemical substances should be referred to by the generic name only. Trade names should not be used. Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name and the name and location of the manufacturer in parentheses.

Appendix B. DSM-V Diagnostic criteria for Major Depressive Disorder

The DSM-5 outlines the following criterion to make a diagnosis of depression. The individual must be experiencing five or more symptoms during the same 2-week period and at least one of the symptoms should be either (1) depressed mood or (2) loss of interest or pleasure.

1. Depressed mood most of the day, nearly every day.
2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day.
3. Significant weight loss when not dieting or weight gain, or decrease or increase in appetite nearly every day.
4. A slowing down of thought and a reduction of physical movement (observable by others, not merely subjective feelings of restlessness or being slowed down).
5. Fatigue or loss of energy nearly every day.
6. Feelings of worthlessness or excessive or inappropriate guilt nearly every day.
7. Diminished ability to think or concentrate, or indecisiveness, nearly every day.
8. Recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.

To receive a diagnosis of depression, these symptoms must cause the individual clinically significant distress or impairment in social, occupational, or other important areas of functioning. The symptoms must also not be a result of substance abuse or another medical condition.

Appendix C. DSM-V Diagnostic criteria for Persistent Depressive Disorder

Persistent Depressive Disorder (Dysthymia)

This disorder represents a consolidation of DSM-IV-defined chronic major depressive disorder and dysthymic disorder.

A. Depressed mood for most of the day, for more days than not, as indicated by either subjective account or observation by others, for at least 2 years.
Note: In children and adolescents, mood can be irritable and duration must be at least 1 year.

B. Presence, while depressed, of two (or more) of the following:
1. Poor appetite or overeating.
2. Insomnia or hypersomnia.
3. Low energy or fatigue.
4. Low self-esteem.
5. Poor concentration or difficulty making decisions.
6. Feelings of hopelessness.

C. During the 2-year period (1 year for children or adolescents) of the disturbance, the individual has never been without the symptoms in Criteria A and B for more than 2 months at a time.
D. Criteria for a major depressive disorder may be continuously present for 2 years.
E. There has never been a manic episode or a hypomanic episode, and criteria have never been met for cyclothymic disorder.
F. The disturbance is not better explained by a persistent schizoaffective disorder, schizophrenia, delusional disorder, or other specified or unspecified schizophrenia spectrum and other psychotic disorder.
G. The symptoms are not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication) or another medical condition (e.g., hypothyroidism).
H. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Appendix D. Prospero Protocol

PROSPERO
International prospective register of systematic reviews

NHS
National Institute for Health Research

UNIVERSITY of York
Centre for Reviews and Dissemination

Systematic review

1. * Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

Does cognitive behavioural analysis system of psychotherapy (CBASP) improve interpersonal functioning for adults with persistent depression?

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.

23/09/2019

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

01/03/2020

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.
Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.
This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

6. * Named contact.

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Karolina Szpak

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Ms Szpak

7. * Named contact email.

Give the electronic mail address of the named contact.

s1794325@sms.ed.ac.uk

8. Named contact address

Give the full postal address for the named contact.

Medical School, Teviot Place, Edinburgh, EH8 9AG

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

0044(0)131 650 3898

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

University of Edinburgh

Organisation web address:

https://www.ed.ac.uk/

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country are**

now mandatory fields for each person.

Ms Karolina Szpak. University of Edinburgh
Mr Tim Bird. University of Edinburgh

12. * Funding sources/sponsors.

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

None

Grant number(s)

13. * Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country are now mandatory fields for each person.**

15. * Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

Does CBASP have an impact on interpersonal functioning among adult population affected by persistent depression?

Is change in interpersonal functioning following a CBASP intervention associated with a change in depressive symptoms among adults affected by persistent depression?

Is CBASP a feasible intervention for adults affected by persistent depression?

16. * Searches.

State the sources that will be searched. Give the search dates, and any restrictions (e.g. language or publication period). Do NOT enter the full search strategy (it may be provided as a link or attachment.)

English

Embase (1980 – October 2019), MEDLINE (1946 to October 2019), PsycINFO (1806 to October 2019), ASSiA (1984 to October 2019), CINAHL (1937 –October 2019).

17. URL to search strategy.

Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies), or upload your search strategy.Do NOT provide links to your search results.

https://www.crd.york.ac.uk/PROSPEROFILES/151685_STRATEGY_20191020.pdf

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Mental health condition

19. * Participants/population.

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion criteria: adult population (16 years old and above) affected by depression, participant has attended CBASP therapy.

Exclusion criteria: attending therapy other than CBASP.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

Cognitive Behavioural Analysis System of Psychotherapy - a psychological therapy developed for persistent depression

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Included studies will include both randomised controlled trials (RCT's) and non randomised controlled trials. For an RCT to be included, the study will need to compare CBASP against another therapy (e.g. CBT), medication, or waiting/list.

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

No restriction on types of study design

Inclusion criteria: studies investigating the effects of one-to-one or group CBASP intervention on psychological well-being, studies involving adults 16 years + suffering from depressive symptoms, published studies using measures of interpersonal or social functioning including randomised controlled trials and non-randomised controlled trials. Exclusion criteria: studies investigating CBASP as a preventative measure, target population not being affected by depression, studies published in a language other than English, children and young people under 16 years old.

23. Context.

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

No restriction on the types of study design

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

Primary outcome: change in interpersonal/social functioning from baseline to the last available follow-up, measured by measures of interpersonal/social functioning e.g. by questionnaires.

* Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Measuring the interpersonal/social functioning pre and post-intervention.

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

Secondary outcome: change in depressive symptoms from baseline to the last available follow-up measured by questionnaires assessing depressive symptoms Secondary outcome: feasibility & acceptability of the CBASP intervention, measured by reviewing drop out rate & by using satisfaction questionnaires.

* Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Measuring the depressive symptoms pre and post-intervention.

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Data will be selected by one researcher and discussed with an independent researcher who acts as a supervisor for the leading researcher. Data extracted from the studies will include: authors, design, sample source, sample size, sample age, concepts measured, measures used, reliability of measure, validity of measures, type of analysis, results (effect size, statistical significance), theoretical framework. Data will be recorded in a Microsoft Word table.

27. * Risk of bias (quality) assessment.

Describe the method of assessing risk of bias or quality assessment. State which characteristics of the studies will be assessed and any formal risk of bias tools that will be used.

As this review focused on studies that look into effects of CBASP intervention on psychological wellbeing, a quality rating measure that has been designed to assess intervention studies influencing public policy was chosen. The Effective Public Health Practice Project (EPHPP, 1998), a quality assessment tool for quantitative studies is a standardised tool has been developed to ensure high quality of systematic reviews investigating the evidence supporting best practice within public health sector. EPHPP assists with an overall methodological rating of the studies across eight different domains i.e. selection bias, study design, confounders, blinding, data collection methods, withdrawals and dropouts, intervention integrity and analysis. The ratings can fall into strong, moderate or weak category. The assessment will be done at the study level. Quality assessment will be carried out by one researcher and discussed with an independent researcher who acts as a supervision for the leading researcher.

28. * Strategy for data synthesis.

Provide details of the planned synthesis including a rationale for the methods selected. This **must not be generic text** but should be **specific to your review** and describe how the proposed analysis will be applied to your data.

No minimum or maximum number of studies set. Results such us intervention effect on interpersonal functioning and depression will be summarised in statistical terms (by identifying means, standard deviations, t/F values, p values & effect sizes, where possible) and compared across the studies. Narrative synthesis of qualitative data will be used to review and synthesise available evidence and will include data such as changes in interpersonal functioning, changes in levels of depression, and drop-out rates.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

No subgroup analysis planned

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

Type of review

Cost effectiveness
No

Diagnostic
No

Epidemiologic
No

Individual patient data (IPD) meta-analysis
No

Intervention
Yes

Meta-analysis
No

Methodology
No

Narrative synthesis
No

Network meta-analysis
No

Pre-clinical
No

Prevention
No

Prognostic
No

Prospective meta-analysis (PMA)
No

Review of reviews
No

Service delivery
No

Synthesis of qualitative studies
No

Systematic review
Yes

Other
No

Health area of the review

Alcohol/substance misuse/abuse
No

Blood and immune system
No

Cancer
No

Cardiovascular
No

Care of the elderly
No

Child health
No

Complementary therapies
No

Crime and justice
No

Dental
No

Digestive system
No

Ear, nose and throat
No

Education
No

Endocrine and metabolic disorders

Wounds, injuries and accidents
No

Violence and abuse
No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.
English

There is an English language summary.

32. * Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

Scotland

33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

Give the link to the published protocol.

Alternatively, upload your published protocol to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

Publishing in scientific journals and disseminate by attending relevant conferences

Do you intend to publish the review on completion?

Yes

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Cognitive Behavioural Analysis System of Psychotherapy

CBASP

social functioning

interpersonal functioning

persistent depression

chronic depression

recurrent depression

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38. * Current review status.

Review status should be updated when the review is completed and when it is published. For newregistrations the review must be Ongoing.
Please provide anticipated publication date

Review_Ongoing

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

40. Details of final report/publication(s).

This field should be left empty until details of the completed review are available.

Give the link to the published review.

Appendix E. The Effective Public Health Practice Project quality assessment tool

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

GLOBAL RATING

COMPONENT RATINGS
Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1	Oversight
2	Differences in interpretation of criteria
3	Differences in interpretation of study

Final decision of both reviewers (circle one):

1	**STRONG**
2	**MODERATE**
3	**WEAK**

Appendix F. Details of the main measures used by the included studies

Measure	Validity & Reliability
BDI-II, Beck's Depression Inventory (Beck, Steer, & Brown, 1996) The BDI-II is a widely used 21-item self-report inventory measuring the severity of depression in adolescents and adults. The BDI-II was revised in 1996 to be more consistent with DSM-IV criteria for depression	Good internal consistency (from 0.83-0.96) and the retest reliability (from 0.73 to 0.96); good criterion-based validity showed good sensitivity and specificity for detecting depression (Wang & Gorenstein, 2013).
GAF, Global Assessment of Functioning (American Psychiatric Association, 1987) GAF covers the range from positive mental health to severe psychopathology and is an overall measure of how patients are doing, administered by a clinician	Reliability studies show that the extreme 20% of raters can account for more than 50% of the spread of scores and that there can be deviations of 20 points or more; overall reliability can be good, but it is lower in the routine clinical setting (Vatnaland, Vatnaland , Friis, & Opjordsmoen, 2007); poor discriminant validity (Grootenboer et al., 2012)
HAM-D/HRSD (Hamilton, 1960) Hamilton Depression Rating Scale The HDRS/HAM-D is clinician-administered outcome measure of depression.	Adequate internal reliability; some items poor contributors to the measurement of depression severity while others have poor interrater and retest reliability; content validity is poor; convergent validity and discriminant validity are adequate (Bagby, Ryder, Shuller, & Marshall, 2004).
IDS-R the Inventory of Depressive Symptomatology, Self-Report (Rush, Gullion, Basoo, Jarrett, & Trivedi, 1996). IDS-R is an outcome measure of depression	Internal consistency ranged from 0.92 to 0.94 for the total sample and from 0.76 to 0.82 for those with current depression; the inter-rater reliability 0.96; good concurrent validity with HAM-D (Rush et al., 1996).
IIP, Inventory of Interpersonal Problems IIP-64/IIP-32 (Horowitz, Alden, Wiggins, & Pincus, 2000) IIP scale designed to assess interpersonal problems in adult people. The main problems contain: sociability, assertiveness, aggression, supportiveness, involvement, caring, openness and dependency. The IIP-64 is based on a circumplex structure of interpersonal problems	For the IIP-32, the significant positive relationship between interpersonal problems and alexithymia indicated good convergent validity; Cronbach's alpha (0.82) and half-split coefficients (0.82) showed that the reliability of this scale is also suitable (Fath, Azzadfallah, Rasoolzadeh, & Rahimi, 2013)

(Horowitz, Dryer, & Krasnoperova, 1997) categorizing interpersonal problems into eight subscales, which can be arranged in two dimensions and define a circumplex. These two dimensions are affiliation (cold/hostile vs. warm/friendly) and dominance (domineering vs. yielding).	For the IIP-64, the properties have been evaluated in both clinical and non-clinical groups and IIP-64 is considered to have acceptable to good reliability and validity (Horowitz et al., 2000)
IMI-C Impact Message Inventory (IMI-C; Kiesler & Schmidt, 2006) IMI assesses a person's interpersonal style indirectly, by asking others what reactions the person typically evokes in them (can be used also as a therapy tool to assess interpersonal pressures)	Acceptable internal consistency; adequate circumplex structure; very good reliability (Kiesler & Schmidt, 2006)
MADRS, Montgomery-Asberg Depression Rating Scale (Montgomery & Asberg, 1979) MADRS is an outcome measure for depression	High inter-rater reliability of the new depression; high correlation with HRSD indicating its validity as a general severity estimate; greater sensitivity to change than that of HRSD (Montgomery & Asberg, 1979)
PEF, Patient Evaluation Form (Brakemeier, Strunk, Normann, & Schramm, 2010) PEF has been designed to measure patients' acceptance and feasibility of CBASP group psychotherapy in an inpatient setting	PEF (n = 65) showed excellent internal consistency with .95 (Cronbach's α) and good test–retest reliability with r = .81 (Saƅas et al., 2018).
SAS-SR , Social Adjustment Scale - Self-Report SAS-SR (Weissman, 1999) SAS-SR is a measure of social adjustment. Questions focus on social functioning (e.g. in relation to work, leisure, relationships, family) during the preceding month.	Satisfactory internal consistency (Cronbach's α = .74; Edwards, Yarvis, Mueller, Zingale, & Wagman, 1978) and convergent validity with measures of depression; differentiated psychiatric patients from a mixed-age community sample (Weissman, Prusoff, Thompson, Harding, & Myers, 1978)
SASS, The Social Adaptation Self-Evaluation Scale (Bosc, Dubini, & Polin, 1997) SASS is used to evaluate different aspects of social interactions, global social attitude, and self-perception. It covers various areas of social	The SASS has been validated and found to be simple to use, reliable and sensitive to changes in different areas of social functioning (Bosc et al., 1997)

functioning including work, spare time, family, environmental organisation, and coping abilities.	
SF-36, Short Form Survey (Ware & Sherbourne 1992) The SF-36 is a widely used 36-item self-report measure of general health and functioning. One of the SF-36 subscales is the Social Functioning subscale which measures to what extent emotional and health problems interfere with social activities.	SF-36 has been adapted and translated into several languages, and its validity and reliability established in several countries (Gandek et al., 1998). Social Functioning subscale was shown to have good construct validity (McHorney, Ware, & Raczek, 1993), high internal consistency, and test-retest reliability (Ruta, Abdalla, Garratt, Coutts, & Russell, 1994)
WHOQOL-BREF World Health Organization Quality of Life assessment (Group, 1998) The WHOQOL-BREF contains two items from the 'overall quality of life', and 'general health' domains of the longer WHOQOL-100, and 24 items each corresponding to the 24 factors of the WHOQOL-100. The 24 items are clustered into four further domains: physical health, psychological health, social relationships, and environment.	A cross-sectional design in 23 countries across the world was used to assess the psychometric properties of WHOQOL-BREF and found sound psychometric properties on internal consistency as well as discriminant and construct validity (Skevington, Lotfy, & O'Connell, 2004). Social relationships scale was shown to have high internal consistency (Cronbach's $\alpha = 0.73$) and adequate construct validity (Oliveira, Carvalho, & Esteves, 2016)

Appendix G. The ethical approval by the West of Scotland Research Ethics Committee

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 5
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ

Ms Karolina Szpak
Clinical Psychologist Trainee
NHS Lothian
Psychology Department, Older Adults
McKinnon House
Royal Edinburgh Hospital
EH10 5HF

Date 14 December 2018

Direct line 0141 232 1809
E-mail WoSREC5@ggc.scot.nhs.uk

Dear Ms Szpak

Study title:	**The use of Structural Equation Modelling as a test of Cognitive Behavioural Analysis System of Psychotherapy (CBASP) model for persistent depression**
REC reference:	**18/WS/0231**
Protocol number:	**CAHSS1810/02**
IRAS project ID:	**250217**

The Research Ethics Committee reviewed the above application at the meeting held on 12 December 2018. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. The following changes should be made to the Demographic Survey:

a) The answers to the third question should also include an answer option for those who

might have been suffering from depression for exactly 2 years ago. Also, since one of the inclusion criteria is that participants will have had depression for at least two years, the answer "less than 2 years" is redundant and should be removed.

b) For the gender question, there should be a "Prefer not to answer" option.

c) With regards to the Qualifications received question, an option of "None" should be added.

2. In the protocol, an inclusion criterion should be added that Adult Mental Health Team Clinicians are willing to participate and identify individuals from their caseloads, as stated in A37-1 of the IRAS form.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Extract of the meeting minutes

Social or scientific value; scientific design and conduct of the study

The Committee noted that the introduction of the IRAS form stated that professional guidelines recommend the use of CBASP. However, further on in the application, it stated that there was little or no research about the effectiveness of CBASP.

The applicant clarified that Cognitive Behavioural Therapy (CBT) is the normal treatment but CBASP has been in use for about five years and is used in Edinburgh. Evidence shows that CBASP is as good as CBT. There is some research on CBASP but not on the theoretical model. More research is needed on the model as a whole.

It was also noted that the secondary research questions are the ones that are the most important. The Committee asked why these were not the principal questions.

Ms Szpak agreed that perhaps she had overlooked this.

It appeared to the Committee that the use of the Luebeck questionnaire was perhaps an add-on to the other validated questionnaires to be used. It was noted that this was originally written in German but that the translation into English was perhaps lost in translation, particularly the scenarios. The Committee asked whether the translation had been tested on anyone yet.

The applicant advised that she was originally planning to use another questionnaire but it was not as suitable as the Luebeck questionnaire. The translation has not yet been tested locally but she was thinking of asking a German colleague to translate the document back into German and then back to English to check whether it still has the same meaning.

The Committee had no further issues with these points and no further action was required.

As a suggestion only, it was strongly recommended that the researcher seeks advice from a professional statistician in order to get the best results from the research.

The applicant agreed that this would be useful.

Recruitment arrangements and access to health information, and fair participant selection

It was noted that the researcher will not differentiate between different types of depression. The inclusion and exclusion criterion is very open. Psychosis is being excluded but it was questioned whether other diagnoses should be excluded.

Ms Szpak confirmed that people who have had chronic depression for more than two years will be included and that only psychosis will be excluded.

The Committee had no further issues with this matter.

It was also suggested that since it is important that Clinicians from the Adult Mental Health Team are willing to participate in the study and identify potential participants, this should be added to the inclusion criteria.

Ms Szpak agreed to do this.

Suitability of supporting information

The Committee agreed that the Demographic Survey required input from a professional statistician to ensure that the questions being asked are relevant and that the answers offer options to cover all possible answers, but are also mutually exclusive. This is particularly important since participants are completing the document by themselves. For example, if the answer to the third question is exactly 2 years, there is no suitable answer. The Committee noted other questions that required attention. If the researcher decides to alter the survey further, this should be submitted to the Committee as a substantial amendment.

Ms Szpak agreed to make the suggested changes.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study Poster]	1	20 November 2018
Covering letter on headed paper [Invitation letter to adult mental health teams]	1	20 November 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional Indemnity Confirmation]		31 July 2018
GP/consultant information sheets or letters [GP letter]	1	20 November 2018
IRAS Application Form [IRAS_Form_26112018]		26 November 2018
Non-validated questionnaire [Demographic survey]	1	20 November 2018
Other [Clinical Trial Liability]		31 July 2018
Other [Certificate of Employers' Liability Insurance(a)]		01 August 2018
Other [Insurance Policy Confirmation]		24 July 2018
Participant consent form [Consent form]	1	20 November 2018
Participant information sheet (PIS) [Participant Information Sheet]	1	20 November 2018
Research protocol or project proposal [Research proposal]	1	20 November 2018

Summary CV for Chief Investigator (CI) [CI's CV]		04 October 2010
Summary CV for supervisor (student research) [Supervisor's CV]		27 August 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow chart of protocol]	1	20 November 2018
Validated questionnaire [Reflective Functioning Questionnaire]	1	20 November 2018
Validated questionnaire [Inventory of Interpersonal Problems]	1	20 November 2018
Validated questionnaire [Patient Health Questionnaire]	1	20 November 2018
Validated questionnaire [Child Abuse and Trauma Scale]	1	20 November 2018
Validated questionnaire [Luebeck Questionnaire of Pre-operational Thinking]	1	20 November 2018

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/WS/0231	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

for
Dr Stewart Campbell
Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments
	"After ethical review – guidance for researchers"
Copy to:	Ms Charlotte Smith, University of Edinburgh Miss Melissa Taylor, NHS Lothian Lead Nation Scotland: nhsg.NRSPCC@nhs.net

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 5
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ

Date 20 December 2018

Direct line 0141 232 1809
E-mail WoSREC5@ggc.scot.nhs.uk

Ms Karolina Szpak
Psychology Department, Older Adults
McKinnon House
Royal Edinburgh Hospital
EH10 5HF

Dear Ms Szpak

Study title: **The use of Structural Equation Modelling as a test of Cognitive Behavioural Analysis System of Psychotherapy (CBASP) model for persistent depression**
REC reference: **18/WS/0231**
Protocol number: **CAHSS1810/02**
IRAS project ID: **250217**

Thank you for your e-submission of 20 December 2018. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 14 December 2018.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Other [Research Protocol]	2	19 December 2018
Other [Demographic survey]	2	19 December 2018

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study Poster]	1	20 November 2018
Covering letter on headed paper [Invitation letter to adult mental health teams]	1	20 November 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional Indemnity Confirmation]		31 July 2018
GP/consultant information sheets or letters [GP letter]	1	20 November 2018

IRAS Application Form [IRAS_Form_26112018]		26 November 2018
Other [Clinical Trial Liability]		31 July 2018
Other [Certificate of Employers' Liability Insurance(a)]		01 August 2018
Other [Insurance Policy Confirmation]		24 July 2018
Other [Research Protocol]	2	19 December 2018
Other [Demographic survey]	2	19 December 2018
Participant consent form [Consent form]	1	20 November 2018
Participant information sheet (PIS) [Participant Information Sheet]	1	20 November 2018
Summary CV for Chief Investigator (CI) [CI's CV]		04 October 2010
Summary CV for supervisor (student research) [Supervisor's CV]		27 August 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow chart of protocol]	1	20 November 2018
Validated questionnaire [Reflective Functioning Questionnaire]	1	20 November 2018
Validated questionnaire [Inventory of Interpersonal Problems]	1	20 November 2018
Validated questionnaire [Patient Health Questionnaire]	1	20 November 2018
Validated questionnaire [Child Abuse and Trauma Scale]	1	20 November 2018
Validated questionnaire [Luebeck Questionnaire of Pre-operational Thinking]	1	20 November 2018

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

18/WS/0231 **Please quote this number on all correspondence**

Yours sincerely

SMacgregor

Sharon Macgregor
REC Manager

Copy to: Miss Melissa Taylor , NHS Lothian Research and Development Office

Lead Nation Scotland: nhsg.NRSPCC@nhs.net

Appendix H. The ethical approval by the NHS Research and Development Office

University Hospitals Division

NHS Lothian

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

RESEARCH & DEVELOPMENT
Room E1.16
Tel: 0131 242 3330
Email:
R&DOffice@nhslothian.scot.nhs.uk

Director:
Professor Tim Walsh

KS/LM

19 February 2019

Ms Karolina Szpak
NHS Lothian
Psychology Department, Older Adults
McKinnon House
Royal Edinburgh Hospital
Edinburgh
EH10 5HF

Dear Ms Szpak

REC No:	18/WS/0231
R&D Project ID No:	2018/0315
Amendment:	Minor amendment dated 1 February 2019
Title of Research:	The use of Structural Equation Modelling as a test of Cognitive Behavioural Analysis System of Psychotherapy (CBASP) model for persistent depression

I am writing in reply to recent correspondence in relation to an amendment(s) to the above project and the subsequent updated documents as follows.

- FAQ sheet for Clinicians Version 1.0, dated 31 January 2019

We have now assessed any consequential changes and can confirm that NHS Lothian management approval is extended to cover the specific changes intimated.

Yours sincerely

Mr Kenneth Scott
NRS Generic Review Manager

Appendix I. Participant Information Sheet

Participant Information Sheet

The use of Structural Equation Modelling as a test of Cognitive Behavioural Analysis System of Psychotherapy

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Our understanding of depression and its treatment has broadened over the past several decades. Cognitive Behavioural Analysis System of Psychotherapy (CBASP) is a psychological therapy that has been developed to specifically address the difficulties of individuals affected by persistent depression. A number of previous studies produced some evidence for relationships between different concepts that are present in the model CBASP is based on. However, there is not much research investigating an overall model of CBASP and therefore, this study will aim to explore the relationships between the concepts within the model i.e. the relationships between adverse childhood experiences, interpersonal difficulties, cognitive-emotional development and persistent depression.

Why have I been asked to take part?

You have been asked to take part as you have been diagnosed as having symptoms of persistent depression by a health professional.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. If you wish to withdraw, you would need to let the research team know by the end of September 2019 before the data analysis takes place.

What will happen if I take part?

To start will you will be asked to read and sign the consent form if you wish to take part in the study. You will be then asked to complete five questionnaires. The questionnaires will ask you about a number of experiences from your life such as the nature of your relationships with other people, your way of thinking about different things and your current symptoms of depression. One of the questionnaires will also ask you about adverse and possibly upsetting experiences from your childhood. Finally, you will be asked about your demographic information including age, gender, the length and onset of your depression etc.

It should take you no more than 30 minutes to answer all the questionnaires and you will be asked to answer them only ONCE. You will then be asked to send back the questionnaires and the signed consent form using the pre-paid return envelope or hand them back to the health professional who invited you to the study.

What are the possible benefits of taking part?

You may not get a direct benefit from taking part in this study. However, the results from this study might inform on the future healthcare of other patients. Testing and evaluating the model CBASP is based on will allow us to better understand how persistent depression develops. Such understanding will help us to identify risk factors associated with persistent depression and develop preventative interventions. It is also likely to lead to more refined therapeutic interventions.

What are the possible disadvantages and risks of taking part?

It is not thought that there are many disadvantages of taking part in this study. However, it is possible that while or after completing the questionnaires you might feel uncomfortable or distressed. One of the questionnaires will ask you about adverse and potentially upsetting experiences from your childhood, for example, experiences of childhood abuse and trauma. Importantly, if you notice yourself getting upset, please remember it is absolutely normal to feel like this when actively thinking about difficult experiences from the past or present. It is also O.K. to stop completing the questionnaires if you feel overwhelmed. Finally, in the event you need to speak to someone about your feelings following taking part in the study, please speak to the healthcare professional who first introduced you to the study. If this is not possible, or you were invited to take part in the study via post please speak to your GP about your feelings. Additionally, there are number of organisations whom you can contact if you are looking for further emotional support. These are:

NHS24 - CALL 111 (urgent health advice out of hours)
Samaritans CALL 116 123 or e-mail jo@samaritans.org (24hrs a day, free helpline providing emotional support to anyone in distress)
Breathing Space CALL 0800 83 85 87 (6pm to 2am on weekdays, and 24 hours at the weekend, free helpline providing psychological counselling to anyone in distress)
Campaign Against Living Miserably CALL 0800 585858 (5pm to midnight, daily, helpline for men who are struggling with mental health)

Open Secret CALL 01324 630 100 (confidential support for survivors of childhood abuse and trauma)

Will my taking part in the study be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

Importantly, if your answers in the questionnaires suggest you or someone in your environment is at risk of harm, the study researchers will need to share this information with the clinician who invited you to the study or if that is not possible with your GP to ensure your own or someone else's safety. If you make a criminal or any other type of disclosure about a particular person, this information might also need to be shared with the clinician who invited you to the study or your GP, and local risk management processes might need to be followed.

The study researchers ask you to provide your date of birth on this form so we can access your medical records in order to obtain your GP's address, your own address and your CHI number. We need your GP's address to let them know about you taking part in this study. The letter to your GP is likely to include your address and CHI number to help to identify you correctly. If we decide to share the information you have provided in the questionnaires with your clinician as part of the risk management, we might also use your medical records to access contact details of the clinician who introduced you to the study. We will inform you about our communication with your clinician via a letter.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor and NHS Institution to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

What if there is a problem?

If you decide to withdraw from the study after returning the questionnaires to the research team, please use the contact e-mail above and let us know you wish to withdraw. If you wish to withdraw, you would need to let the research team know by the end of September 2019 before the data analysis takes place.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen to the results of the study?

Once enough participants have returned the signed consent forms and the questionnaires, the collected data will be anonymised and analysed using a statistical programme. At the end of the research which is scheduled for April 2020 we will share the results with the clinical teams or the research team we have recruited the participants from. You are welcome to contact the team that invited you to the study to find out about the results. The research team will also aim to publish results of the study as a thesis and as an article in a peer-reviewed journal. You will not be identifiable in any published results.

When you agree to take part in a research study, the anonymised information you provided to researchers may be provided to researchers running other research studies in this organisation and other organisations These organisations may be universities, NHS organisations or companies involved in health and social care research. Your information will only be used to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and social care research and cannot be used to contact you or affect your care.

Who is organising the research and why?

This study has been organised/sponsored by the University of Edinburgh.

Who has reviewed the study?

The study proposal has been reviewed by the research team from the University of Edinburgh and by a clinical supervisor within the NHS. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from xxx REC. NHS management approval has also been obtained.

If you have any further questions about the study please contact Karolina Szpak at s1794325@sms.ed.ac.uk or Dr Timothy Bird at timothy.bird@ed.ac.uk

If you would like to discuss this study with someone independent of the study please contact: Helen Griffiths, Programme Director of the University of Edinburgh/NHS Scotland Clinical Psychology training programme
School of Health in Social Science
Contact no: +44 (0) 131 6503482
E-mail: helen.griffiths@ed.ac.uk
If you wish to make a complaint about the study please contact NHS Lothian:
NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2 - 4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5708
complaints.team@nhslothian.scot.nhs.uk.

If you wish to take part in this study after reading the information sheet, please read and sign the consent form, and complete the attached questionnaires. Once you have completed all the questionnaires, please send the signed consent sheet and the questionnaires to the research team using the pre-paid return envelope. Alternatively, hand the signed consent form and the completed questionnaires back to the healthcare professional who invited you take to part in the study.

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at www.accord.scot.

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; https://www.hra.nhs.uk/information-about-patients/.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Data Protection Officer contact information: **University of Edinburgh**
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net

Appendix J. Participant Consent Form

CONSENT FORM
[CBASP model study]

Please initial box

1. I confirm that I have read and understand the information sheet (Version 1, 20/11/2018) for the above study and have had the opportunity to consider the information and ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsors (NHS Lothian and the University of Edinburgh) or from other NHS Boards where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records. ☐

4. I agree to my anonymised data being used for future ethically approved studies. ☐

5. I agree to my General Practitioner being informed of my participation in this study

7. I agree to take part in the above study. ☐

Name of Participant

_____

Date of Birth

_____

Today's Date

_____

Signature

_____

Please note: Original of the Consent form (x1) to be retained in site file. Copy of the Consent form (x1) to be included in patient notes. Copy of the Consent form (x1) to be retained by the participant.

Appendix K. Information sheet for clinicians

INFORMATION SHEET FOR CLINICIANS
The use of Structural Equation Modelling as a test of Cognitive Behavioural Analysis System of Psychotherapy

This sheet was developed in order to address frequently asked questions by clinicians who are interested in finding more about the above study.

WHAT DOES A CLINICIAN HAVE TO DO?
The clinician is asked to briefly introduce the potential participant to the study and if the person is interested in finding out more about it, the clinician is asked to give the person an envelope, provided by the researcher, containing all the required paperwork such as a participant information sheet and consent form, as well as questionnaires that the person will be asked to complete if he/she decides to take part.

WHAT ARE THE INCLUSION AND EXCLUSION CRITERIA?
We are looking for participants who have been affected by persistent depression (depressed mood for at least the last 2 years and, during the last 2 years, not without symptoms meeting the criteria for persistent depressive disorder for more than 2 months at a time). Please see the details of the inclusion and exclusion criteria as well as the DSM-V diagnostic criteria for persistent depression on page 3.

WHY IS THE STUDY HELPFUL?
The study aims to explore a theoretical model behind CBASP - a therapy for chronic depression (Cognitive Behavioural Analysis System of Psychotherapy). Results of this study are likely to increase our understanding of chronic depression and how it develops throughout our lifetime. Increased understanding of the model behind chronic depression will allow us to develop more effective therapies for this condition. Importantly, increased understanding of the risk factors associated with the chronic depression might help to prevent it altogether.

WHAT WILL THE PARTICIPANT HAVE TO DO?
The person will be given an envelope with all the paperwork that needs to be completed. **Yellow pages**, all stapled together inside the envelope, provide information for the person interested in the study to learn more about it before deciding whether to take part in it

White pages, also stapled together inside the envelope, are to be completed and sent back by the person if they decide to take part in the study. The white pages should take **no more than 30minutes** to complete. White pages include the consent form the person needs to read and sign, and a demographics questionnaire. They also include 5 additional questionnaires addressing areas such as adverse childhood experiences, cognitive and emotional difficulties, interpersonal difficulties and symptoms of depression.

Once the person completes all of the questionnaires and the consent form (i.e. all the white sheets), they will be asked to send them back in the same envelope they found the paperwork in. The envelope is addressed to the researchers who are conducting the study.

WILL THE INFORMATION COLLECTED THROUGH THE QUESTIONNAIRES BE CONFIDENTIAL?

All the information collected during the course of the research will be kept confidential. The researchers ask the participants to provide them with their name

and D.O.B. on the consent form so the researchers can inform the person's GP about them taking part in the study.

WHAT IF THE PARTICIPANT BECOMES UPSET?

The participant does not have to continue completing the questionnaires if he/she feels overwhelmed. If the participant feels that he/she needs to speak to someone about their feelings, they can speak to the healthcare professional who first introduced them to the study, or if this is not possible, to their GP. Additionally, details of organisations offering relevant emotional support are listed within the participant's information sheet.

If you have any further questions about the study please contact Karolina Szpak at s1794325@sms.ed.ac.uk or Dr Timothy Bird at timothy.bird@ed.ac.uk

THANK YOU FOR SUPPORTING THE STUDY

Inclusion criteria:

- 18 years old or above
- currently attending NHS Adult Mental Health Service (e.g. for treatment, assessment or triage)
- depressed for at least 2 years
- during the last 2 years participant was never without the symptoms meeting criteria for persistent depressive disorder for more than 2 months at a time
- fluent in spoken and written English

Exclusion criteria:

- diagnosis of psychosis
- lack of capacity to give consent

DSM-V Diagnostic criteria for Persistent Depressive Disorder

Persistent Depressive Disorder (Dysthymia) 300.4 (F34.1)

This disorder represents a consolidation of DSM-IV-defined chronic major depressive disorder and dysthymic disorder.

A. Depressed mood for most of the day, for more days than not, as indicated by either subjective account or observation by others, for at least 2 years.
Note: In children and adolescents, mood can be irritable and duration must be at least 1 year.

B. Presence, while depressed, of two (or more) of the following:
1. Poor appetite or overeating.
2. Insomnia or hypersomnia.
3. Low energy or fatigue.
4. Low self-esteem.
5. Poor concentration or difficulty making decisions.
6. Feelings of hopelessness.

C. During the 2-year period (1 year for children or adolescents) of the disturbance, the individual has never been without the symptoms in Criteria A and B for more than 2 months at a time.
D. Criteria for a major depressive disorder may be continuously present for 2 years.

E. There has never been a manic episode or a hypomanic episode, and criteria have never been met for cyclothymic disorder.
F. The disturbance is not better explained by a persistent schizoaffective disorder, schizophrenia, delusional disorder, or other specified or unspecified schizophrenia spectrum and other psychotic disorder.
G. The symptoms are not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication) or another medical condition (e.g., hypothyroidism).
H. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Appendix L. Author guidelines for the Journal of Affective Disorders

Description

The Journal of Affective Disorders publishes papers concerned with affective disorders in the widest sense: depression, mania, anxiety and panic. It is interdisciplinary and aims to bring together different approaches for a diverse readership. High quality papers will be accepted dealing with any aspect of affective disorders, including biochemistry, pharmacology, endocrinology, genetics, statistics, epidemiology, psychodynamics, classification, clinical studies and studies of all types of treatment.

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• Ensure all figure and table citations in the text match the files provided
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• Journal policies detailed in this guide have been reviewed
• Referee suggestions and contact details provided, based on journal requirements

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